醫療器材管理法相關法規及公告彙編

衛生福利部食品藥物管理署
中華民國112年12月

Compilation of Laws and Regulations Related to Medical Devices Management and Official Announcements

Ministry of Health and Welfare

Food and Drug Administration

Republic of China (Taiwan)

December, 2023

Translated by RegDesk AI

目錄

醫療器材管理法相關法規 1
【醫療器材管理法】(109.01.15 發布) 2
【醫療器材管理法施行細則】(110.04.26 發布) 22
【醫療器材分類分級管理辦法】(112.08.22 修正) 29
【醫療器材技術人員管理辦法】(110.04.01 發布) 31
【醫療器材來源流向資料建立及管理辦法】(110.04.20 發布) 35
【醫療器材製造業者設置標準】(109.12.10 發布) 38
【醫療器材品質管理系統準則】(110.04.14.發布) 40
【醫療器材品質管理系統檢查及製造許可核發辦法】(110.02.02 發布) 59
【醫療器材委託製造作業準則】(110.04.15.發布) 62
【醫療器材優良運銷準則】(110.04.13 發布) 64
【醫療器材優良運銷檢查及運銷許可核發辦法】(110.01.29 發布) . . 72
【醫療器材許可證核發與登錄及年度申報準則】(112.11.27 修正) . . 75
【特定醫療器材專案核准製造及輸入辦法】(110.04.22 發布) 103
【醫療器材優良臨床試驗管理辦法】(110.04.09 發布) 110
【醫療器材安全監視管理辦法】(110.04.28 發布) 124
【醫療器材嚴重不良事件通報辦法】(110.04.28 發布) 127
【輸入醫療器材邊境抽查檢驗辦法】(111.07.08 修正) 130
【醫療器材回收處理辦法】(110.04.28 發布) 138
【醫療器材行政規費收費標準】(112.02.23 修正) 142
【醫療器材檢驗委任或委託作業辦法】(110.04.30 發布) 145
【醫療器材檢驗機構認證及委託認證管理辦法】(110.04.29 發布) . 147
【醫療器材管理事項委託及受託機構認證作業辦法】(110.04.29 發布) 154
【醫療器材創新科技研究發展獎勵辦法】(110.04.29 發布) 160

I

Table of Contents

Regulations Related to the Medical Devices Act 1

[Medical Devices Act] (Promulgated 2020.01.15) 2

[Enforcement Rules of the Medical Devices Act] (Promulgated 2021.04.26) 22

[Regulations for Classification and Risk-Based Management of Medical Devices] (Amended 2023.08.22) 29

[Regulations for Management of Technical Personnel in Medical Devices] (Promulgated 2021.04.01) 31

[Regulations for Establishment and Management of Traceability Data of Medical Devices] (Promulgated 2021.04.20) 35

[Standards for Establishment of Medical Device Manufacturers] (Promulgated 2020.12.10) 38

[Guidelines for Medical Device Quality Management Systems] (Promulgated 2021.04.14) 40

[Regulations on Inspection of Medical Device Quality Management Systems and Issuance of Manufacturing Permits] (Promulgated 2021.02.02) 59

[Guidelines for Contract Manufacturing Operations of Medical Devices] (Promulgated 2021.04.15) 62

[Guidelines for Good Distribution Practices of Medical Devices] (Promulgated 2021.04.13) 64

[Regulations on Inspection of Good Distribution Practices of Medical Devices and Issuance of Distribution Permits] (Promulgated 2021.01.29) .. 72

[Guidelines for Issuance, Registration, and Annual Declaration of Medical Device Licenses] (Amended 2023.11.27) .. 75

[Regulations for Special Approval of Manufacturing and Importation of Certain Medical Devices] (Promulgated 2021.04.22) 103

[Regulations for Good Clinical Practice in Medical Device Clinical Trials] (Promulgated 2021.04.09) 110

[Regulations for Safety Surveillance of Medical Devices] (Promulgated 2021.04.28) 124

[Regulations for Reporting of Serious Adverse Events of Medical Devices] (Promulgated 2021.04.28) 127

[Regulations for Border Inspection and Sampling of Imported Medical Devices] (Amended 2022.07.08) 130

[Regulations for Recall and Handling of Medical Devices] (Promulgated 2021.04.28) 138

[Standards for Collection of Administrative Fees for Medical Devices] (Amended 2023.02.23) 142

[Regulations for Commissioned or Entrusted Inspections of Medical Devices] (Promulgated 2021.04.30) 145

[Regulations for Certification and Entrusted Certification for Medical Device Inspection Agencies] (Promulgated 2021.04.29) . 147

Translated by RegDesk AI

[Regulations for Commissioned Management of Medical Device Regulatory Affairs and Certification of Entrusted Agencies] (Promulgated 2021.04.29) 154

[Regulations for Incentive Awards for Research and Development of Innovative Medical Device Technology] (Promulgated 2021.04.29) 160

Translated by RegDesk AI

醫療器材管理法相關公告.....162
【醫療器材商(藥局)分設醫療器材自動販賣機免各別辦理營業處所販賣業許可執照】.....165
【藥局得兼營醫療器材零售業務之範圍及種類】.....166
【通訊交易通路販售醫療器材之品項及應遵行事項】.....167
【得以自動販賣機販售之醫療器材種類及其販售之應遵循事項】.170
【應建立與保存來源及流向資料之醫療器材及應申報來源及流向資料之醫療器材品項】.....173
【免取得醫療器材製造許可品項】.....184
【醫療器材管理法第二十四條應建立醫療器材優良運銷系統之醫療器材品項及其販賣業者】.....188
【應以登錄方式取得上市許可之醫療器材品項】.....191
【特定醫療器材品項應符合之規格、檢驗方法及性能】.....194
【醫療器材標籤、說明書或包裝得免刊載製造日期及有效期間，或保存期限之規定】.....196
【特定醫療器材之標籤、說明書或包裝應加註警語及注意事項】.198
【依醫療器材管理法第二十五條第四項規定，由中央主管機關逕予登錄及註銷原許可證者，產品標籤、說明書或包裝相關規定】.....207
【醫療器材標籤應刊載單一識別碼規定】.....208
【得以電子化說明書取代中文說明書之醫療器材品項及其標籤或包裝應加註事項】.....214
【無顯著風險之醫療器材臨床試驗態樣】.....216
【除日戴型每日拋棄式隱形眼鏡外，其餘隱形眼鏡之廣告，以登載於專供醫事人員閱聽之醫療刊物、傳播工具，或專供醫事人員參與之醫療學術性相關活動為限】.....218
【應執行安全監視之醫療器材品項】.....219
【使用醫療器材蒐集、處理或利用個人資訊者，其替代書面同意之方式】.....232

II

Announcements Related to the Medical Devices Act 162

【Exemption for Medical Device Vendors (Pharmacies) from Obtaining Separate Sales Site Licenses for Installing Medical Device Vending Machines】 165

【Scope and Types of Medical Device Retail Business that Pharmacies May Also Operate】 166

【Categories of Medical Devices Permitted for Sale via Remote Commerce Channels and Compliance Requirements】 167

【Categories of Medical Devices Permitted for Sale via Vending Machines and Sale Compliance Requirements】 . 170

【Medical Devices for Which Source and Flow Data Must Be Established and Retained, and Types Requiring Source and Flow Data Reporting】 173

【Medical Device Items Exempt from Manufacturing Permit Requirements】 184

【Medical Device Items and Vendors Required to Establish a Good Distribution Practice System as Stipulated in Article 24 of the Medical Devices Act】 188

【Medical Device Categories Requiring Market Authorization by Registration】 191

【Specifications, Testing Methods, and Performance Requirements for Specific Medical Device Items】 194

【Regulations Allowing Labels, Instructions, or Packaging of Medical Devices to Be Exempt from Stating the Manufacturing Date, Expiry Date, or Shelf Life】 196

【Required Warnings and Notices on the Labels, Instructions, or Packaging of Specific Medical Devices】 . 198

【Label, Instruction, or Packaging Requirements for Products Registered and Revoked by the Central Competent Authority Pursuant to Article 25, Paragraph 4 of the Medical Devices Act】 207

【Regulations Requiring Unique Device Identifiers on Medical Device Labels】 208

【Medical Device Items for Which Electronic Instructions May Replace Chinese-Language Instructions, and Items to Be Noted on Labels or Packaging】 214

【Types of Clinical Trials for Medical Devices with No Significant Risk】 216

【Except for Daily-Wear Daily Disposable Contact Lenses, Advertising of Other Contact Lenses Is Limited to Medical Publications, Media, or Academic Activities Exclusively Provided for Medical Personnel】 218

【Medical Device Items Requiring Safety Surveillance】 219

【Methods for Substituting Written Consent When Collecting, Processing, or Utilizing Personal Information with Medical Devices】 232

Translated by RegDesk AI

醫療器材管理法相關法規

1

Regulations Related to the Medical Devices Act

Translated by RegDesk AI

【醫療器材管理法】(109.01.15發布)

第一章　總則

第1條

為保障國人使用醫療器材之安全、效能及品質、增進國民健康及強化醫療器材管理，特制定本法。

第2條

本法所稱主管機關：在中央為衛生福利部；在直轄市為直轄市政府；在縣（市）為縣（市）政府。

第3條

本法所稱醫療器材，指儀器、器械、用具、物質、軟體、體外診斷試劑及其相關物品，其設計及使用係以藥理、免疫、代謝或化學以外之方法作用於人體，而達成下列主要功能之一者：

一、診斷、治療、緩解或直接預防人類疾病。

二、調節或改善人體結構及機能。

三、調節生育。

前項醫療器材之分類、風險分級、品項、判定原則及其他相關事項之辦法，由中央主管機關定之。

第一項第二款屬非侵入性、無危害人體健康之虞及使用時毋需醫事人員協助之輔具，得報請中央主管機關核准，免列為前項醫療器材之品項。

前項輔具係指協助身心障礙者改善或維護身體功能、構造，促進活動及參與，或便利其照顧者照顧之裝置、設備、儀器及軟體等產品。

第4條

本法所稱試驗用醫療器材，指醫療效能及安全尚未經證實，專供臨床試驗用之醫療器材。

第5條

本法所稱醫療器材臨床試驗，指醫療機構或經中央主管機關公告之機構（以下簡稱臨床試驗機構），對受試者所為有關醫療器材安全或效能之系統性研究。

第6條

本法所稱醫療器材廣告，指利用傳播方法，宣傳醫療效能，以達招徠銷售醫療器材為目的之行為。

Medical Devices Act (Promulgated on 2020.01.15)

Chapter 1 - General Provisions

Article 1

This Act is hereby enacted to safeguard the safety, effectiveness, and quality of medical devices for the public, to enhance national health, and to strengthen the management of medical devices.

Article 2

The term "Competent Authority" as used in this Act refers to the Ministry of Health and Welfare at the central government level; municipal governments at the municipality level; and county (city) governments at the county (city) level.

Article 3

The term "medical device" as used in this Act refers to any instrument, appliance, apparatus, material, software, in vitro diagnostic reagent, or related articles, which are designed and intended to be used on human bodies for achieving any of the following principal purposes, by means other than pharmacology, immunology, metabolism, or chemical action:

1. Diagnosis, treatment, alleviation, or direct prevention of human diseases.

2. Regulation or improvement of human body structure and function.

3. Regulation of reproduction.

The classification, risk grading, itemization, determination principles, and other related matters concerning medical devices mentioned in the preceding paragraph shall be prescribed by the central competent authority.

Assistive devices under subparagraph 2 of paragraph 1 that are non-invasive, free from potential harm to human health, and require no assistance from healthcare professionals during use, may be submitted for approval by the central competent authority for exemption from being listed as items of medical devices as set forth in the preceding paragraph.

The term "assistive devices" in the preceding paragraph refers to devices, equipment, instruments, software, and similar products that assist persons with physical or mental disabilities to improve or maintain bodily function and structure, promote activity and participation, or facilitate care by their caregivers.

Article 4

The term "medical device for investigational use" as used in this Act refers to a medical device which has not yet been confirmed for efficacy and safety and is intended exclusively for use in clinical trials.

Article 5

The term "medical device clinical trial" as used in this Act refers to systematic research conducted by medical institutions or institutions announced by the central competent authority (hereinafter referred to as clinical trial institutions) on subjects, concerning the safety or effectiveness of medical devices.

Article 6

The term "medical device advertisement" as used in this Act refers to activities utilizing any means of communication to publicize medical efficacy for the purpose of soliciting the sale of medical devices.

Translated by RegDesk AI

採訪、報導或宣傳之內容暗示或影射醫療器材之醫療效能，以達招徠銷售醫療器材為目的者，視為醫療器材廣告。

第7條

本法所稱標籤，指標示於醫療器材或其包裝上之文字、圖畫或記號。

本法所稱說明書，指對醫療器材安全、效能及使用等產品資訊之相關說明資料。

第8條

本法所稱不良醫療器材，指醫療器材經稽查或檢驗有下列情形之一者：

一、使診斷發生錯誤，或含有毒、有害物質，致危害人體健康。

二、依標籤或說明書刊載之用法，作正常合理使用時易生危險，或危害人體健康之虞。

三、超過有效期間或保存期限。

四、性能或規格與查驗登記、登錄之內容不符，或與第三十條第二項之公告內容不符。

五、未依查驗登記核准儲存條件保存。

六、混入或附著影響品質之異物。

七、經中央主管機關公告之其他瑕疵。

【相關罰則】第一款~§60；第二款至第五款、第七款~§64；第六款~§71

第9條

本法所稱醫療器材商，指醫療器材製造業者或販賣業者。

第10條

本法所稱醫療器材製造業者，指下列二類業者：

一、從事醫療器材製造、包裝、貼標、滅菌或最終驗放。

二、從事醫療器材設計，並以其名義於市場流通。

第11條

本法所稱醫療器材販賣業者，指經營醫療器材之批發、零售、輸入、輸出、租賃或維修之業者。

第12條

本法所稱醫事機構，指醫療法第十條第一項所定醫事人員依其專門職業法規規定申請核准開業之機構。

第二章　製造販賣之管理

3

If the content of interviews, reports, or publicity implicitly or explicitly suggests or refers to the medical efficacy of medical devices with the intent to solicit sales of medical devices, it shall be deemed as medical device advertising.

Article 7

The term "label" as used in this Act refers to the text, drawings, or markings displayed on medical devices or their packaging.

The term "package insert" as used in this Act refers to relevant explanatory materials regarding product information such as the safety, efficacy, and use of medical devices.

Article 8

The term "defective medical device" as used in this Act refers to any medical device found, upon inspection or examination, to have any of the following circumstances:

1. Causes diagnostic errors, or contains toxic or harmful substances, thereby endangering human health.

2. Likely to cause danger or endanger human health when used normally and reasonably according to the method indicated on the label or package insert.

3. Exceeded the period of efficacy or storage period.

4. Performance or specifications do not conform to the content registered or listed, or do not conform to the publicly announced content under Paragraph 2, Article 30.

5. Not stored in accordance with the storage conditions approved in the registration inspection.

6. Contaminated with or attached with foreign substances affecting quality.

7. Other defects publicly announced by the central competent authority.

[Relevant Penalties] Item 1~§60; Items 2 to 5, and Item 7~§64; Item 6~§71

Article 9

The term "medical device enterprises" as used in this Act refers to medical device manufacturers or distributors.

Article 10

The term "medical device manufacturers" as used in this Act refers to the following two categories of enterprises:

1. Those engaged in the manufacturing, packaging, labeling, sterilization, or final release of medical devices.

2. Those engaged in the design of medical devices, and market such devices under their own name.

Article 11

The term "medical device distributors" as used in this Act refers to enterprises engaged in the wholesale, retail, import, export, leasing, or repair of medical devices.

Article 12

The term "medical institutions" as used in this Act refers to institutions established by medical personnel as defined in Paragraph 1, Article 10 of the Medical Care Act, which have applied for and obtained approval to operate in accordance with the relevant professional regulations.

Chapter II Management of Manufacturing and Distribution

Translated by RegDesk AI

第13條

非醫療器材商，除另有規定外，不得為第十條及第十一條所定之業務。

申請為醫療器材商者，應經直轄市、縣（市）主管機關核准登記，領得許可執照後，始得營業；其登記事項有變更時，應辦理變更登記。

醫療器材商應於登記處所製造、販賣或供應醫療器材；其分設製造場所或營業處所者，應依前項規定各別辦理醫療器材商登記，但經中央主管機關公告者，免各別辦理營業處所販賣業許可執照或於登記處所販賣或供應醫療器材。

第二項申請醫療器材商，如非有公司登記或商業登記者，需檢附其目的事業主管機關同意函。

第二項之醫療器材商，應依工業團體法或商業團體法之規定加入同業公會。

【相關罰則】第一項、第二項、第三項~§70

第14條

申請登記為醫療器材製造業者，得兼營其已完成登錄或經核准之自製醫療器材之批發、零售、輸出、租賃、維修或其自用原料輸入之業務，免請領醫療器材販賣業許可執照。

藥局得兼營中央主管機關公告等級之醫療器材零售業務；其兼營醫療器材零售業務者，適用本法醫療器材販賣業者之規定，但得免請領醫療器材販賣業許可執照。

醫事機構為執行業務之必要，得供應業務相關之醫療器材，並得免請領醫療器材販賣業許可執照。但非屬執行業務提供病人使用，而係販賣、零售醫療器材者，仍應依本法第十三條第二項規定，辦理醫療器材商登記。

第15條

醫療器材製造業者及從事輸入或維修之販賣業者，應視醫療器材類別，聘僱技術人員。

前項醫療器材類別、技術人員資格及比例、教育訓練之課程時數及其他相關事項之辦法，由中央主管機關定之。

醫療器材製造業者及從事輸入或維修之販賣業者依第一項聘僱之技術人員，因解聘、辭聘或其他原因不能執行其任務而未另行聘僱者，主管機關應令其限期改善；屆期未改善者，應即停止醫療器材之製造、輸入或維修業務。

【相關罰則】第一項~§71

第16條

醫療器材商申請停業，應將醫療器材商許可執照及醫療器材許可證繳交直

Article 13

Except as otherwise provided, non-medical device enterprises may not engage in the business activities prescribed in Articles 10 and 11.

Applicants who wish to become medical device enterprises must obtain approval and registration from the municipal, county (city) competent authority, and acquire a business license before commencing operations; if there is any change in the registration particulars, an amendment registration must be processed.

Medical device enterprises shall manufacture, sell, or supply medical devices at their registered premises; if they establish separate manufacturing or business locations, separate registration as medical device enterprises must be carried out for each location according to the previous paragraph. However, if otherwise announced by the central competent authority, exemptions may be made for individual business location sales licenses or for selling and supplying medical devices at the registered premises.

For applicants in the second paragraph who do not possess company or commercial registration, a letter of consent from the competent authority of the intended business must be submitted.

Medical device enterprises under paragraph two must join trade associations in accordance with the Industrial Association Act or the Commercial Association Act.

[Related Penalty Provisions] Paragraphs 1, 2, and 3 ~ §70

Article 14

Applicants registering as medical device manufacturers may concurrently engage in the wholesale, retail, export, leasing, repair, or importation of self-used raw materials for medical devices that have been duly listed or approved for their own manufacture, without needing to obtain a medical device sales business license.

Pharmacies may concurrently conduct retail business for medical devices of the grade(s) announced by the central competent authority; when engaging in concurrent retail sales of medical devices, the provisions for medical device sales enterprises under this Act shall apply, but there is no need to obtain a medical device sales business license.

Medical institutions, as necessary for carrying out their business, may supply relevant medical devices and are exempted from obtaining a medical device sales business license. However, if the activity involves selling or retailing medical devices not for the purpose of carrying out business (i.e., not directly provided for patients' use as part of medical services), registration as a medical device enterprise must still be completed in accordance with Article 13, Paragraph 2 of this Act.

Article 15

Medical device manufacturers and sales enterprises engaged in the import or repair of medical devices must, in accordance with the category of medical devices, employ technical personnel.

Regulations regarding the categories of medical devices in the preceding paragraph, qualifications and ratios of technical personnel, the number of hours for educational and training courses, and other related matters shall be prescribed by the central competent authority.

Should a medical device manufacturer or a sales enterprise engaged in import or repair no longer have the technical personnel employed in accordance with Paragraph 1 due to dismissal, resignation, or other reasons and fail to employ a replacement, the competent authority shall order the business to make corrections within a prescribed time limit. If the correction is not made within the time limit, the manufacture, import, or repair of medical devices must be immediately suspended.

[Related Penalty Provisions] Paragraph 1 ~ §71

Article 16

Translated by RegDesk AI

If a medical device enterprise applies for suspension of business, it must submit its medical device enterprise business license and medical device licenses to the municipality, county (city) competent authority.

Translated by RegDesk AI

轄市、縣（市）主管機關，於執照上記明停業理由及期限，並於核准復業時發還之；每次停業期間，不得超過一年。

醫療器材商應於停業期滿前，申請復業、繼續停業或歇業登記；屆期未申請者，經直轄市、縣（市）主管機關查核發現原址已無營業事實，應由原發證照之主管機關，將其有關證照逕予廢止。

醫療器材商申請歇業時，應將其所領醫療器材商許可執照及醫療器材許可證一併繳銷；未繳銷者，由原發證照之主管機關廢止之。

違反本法規定，經主管機關處分停業者，其證照繳交、記明及發還，依第一項規定辦理。

第17條

醫療器材商不得購入或承租未經查驗登記、登錄或非醫療器材商供應之醫療器材。

第18條

中央主管機關應視醫療器材使用風險，公告特定醫療器材之種類、品項，限制其販售或供應型態。

【相關罰則】§70

第19條

經中央主管機關公告一定風險等級之醫療器材，醫療器材商及醫事機構應建立與保存產品直接供應來源及流向之資料。

經中央主管機關公告之品項，前項建立及保存之資料應向中央主管機關申報。

前二項資料之範圍、建立與保存方式、保存年限、申報內容、方式及其他應遵行事項之辦法，由中央主管機關定之。

【相關罰則】第一項、第二項、第三項~§71

第20條

醫療器材製造業者之場所設施、設備及衛生條件，應符合醫療器材製造業者設置標準。

前項醫療器材製造業者設置標準，由中央主管機關會同中央工業主管機關定之。

【相關罰則】第一項~§68

第21條

從事第十條第一款製造之醫療器材製造業者，應依工廠管理輔導法規定，

5

Municipal and county (city) competent authorities shall indicate the reason and period of business suspension on the license, and shall return it upon approval of resumption of business; the period of suspension shall not exceed one year each time.

Medical device dealers shall, before the expiration of the suspension period, apply for resumption of business, extension of suspension, or cancellation of registration; those who fail to apply upon expiration and are found by the municipal or county (city) competent authority to have already ceased business operations at the original location shall have the relevant licenses revoked by the original issuing authority without further notice.

When a medical device dealer applies for cancellation of business, they shall surrender both the medical device dealer permit and the medical device license; if not surrendered, the issuing authority shall revoke them.

If a medical device dealer is ordered to suspend business for violating the provisions of this Act, the submission, indication, and return of the licenses shall be handled in accordance with the provisions of Paragraph 1.

Article 17

Medical device dealers shall not purchase or lease medical devices that are not inspected and registered, recorded, or supplied by other medical device dealers.

Article 18

The central competent authority shall, based on the risk of use of medical devices, announce specific types and items of medical devices for which the manner of sale or supply is restricted.

[Relevant Penalties] §70

Article 19

For medical devices of certain risk levels announced by the central competent authority, medical device dealers and medical institutions shall establish and retain data on the direct source and distribution of the products.

For items announced by the central competent authority, the data established and retained in the preceding paragraph shall be reported to the central competent authority.

The regulations regarding the scope of data in the preceding two paragraphs, establishment and retention methods, retention period, reporting content, methods, and other compliance matters shall be prescribed by the central competent authority.

[Relevant Penalties] Paragraphs 1, 2, 3 ~ §71

Article 20

The premises, facilities, equipment, and sanitary conditions of medical device manufacturers shall comply with the Establishment Standards for Medical Device Manufacturers.

The standards for establishing medical device manufacturers as prescribed in the preceding paragraph shall be jointly formulated by the central competent authority and the central industrial competent authority.

[Relevant Penalties] Paragraph 1 ~ §68

Article 21

Medical device manufacturers engaging in the manufacturing specified in Subparagraph 1, Article 10, shall comply with the Factory Management and Assistance Act.

Translated by RegDesk AI

辦理工廠登記。但依工廠管理輔導法規定免辦理工廠登記，或經中央主管機關核准為研發而製造者，不在此限。

第22條

醫療器材製造業者應建立醫療器材品質管理系統，就場所設施、設備、組織與人事、生產、品質管制、儲存、運銷、客戶申訴及其他事項予以規範，並應符合品質管理系統準則。

醫療器材製造業者依前項準則規定建立醫療器材品質管理系統，並報中央主管機關檢查合格取得製造許可後，始得製造。但經中央主管機關公告之品項，免取得製造許可。

輸入醫療器材之國外製造業者，準用前二項規定，並由中央主管機關定期或依實際需要赴國外製造場所檢查之。

第一項之品質管理系統準則及第二項檢查內容與方式、許可之條件、程序、審查、核發、效期、變更、撤銷或廢止及其他應遵行事項之辦法，由中央主管機關定之。

【相關罰則】第一項、第二項、第三項~§68；第四項~§70

第23條

醫療器材製造業者，非經中央主管機關核准，不得委託其他製造業者製造或接受委託製造醫療器材。

醫療器材販賣業者不得製造醫療器材。但經中央主管機關核准其委託其他醫療器材製造業者製造者，不在此限。

前二項委託製造之申請文件、產品責任、契約規定、標籤、包裝及其他相關作業事項之準則，由中央主管機關定之。

【相關罰則】第一項、第二項~§70

第24條

經中央主管機關公告之醫療器材及其販賣業者，應建立醫療器材優良運銷系統，就產品之儲存、運銷、服務、人員配置及其他相關作業事項予以規範，並應符合醫療器材優良運銷準則。

醫療器材販賣業者依前項準則規定建立醫療器材優良運銷系統，並報中央主管機關檢查合格，取得運銷許可後，始得批發、輸入或輸出。

第一項之優良運銷準則及前項檢查內容與方式、許可之條件、程序、審查、核發、效期、變更、撤銷或廢止及其他應遵行事項之辦法，由中央主管機關定之。

【相關罰則】第一項、第二項~§70；第三項~§71

6

Factory Registration Procedures. However, those exempted from factory registration under the Factory Management and Counseling Act, or those approved by the central competent authority for manufacturing for research and development purposes, are not subject to this restriction.

Article 22

Medical device manufacturers shall establish a medical device quality management system, which shall regulate matters such as site facilities, equipment, organization and personnel, production, quality control, storage, distribution, customer complaints, and other related matters, and shall comply with the quality management system standards.

Medical device manufacturers shall establish a medical device quality management system in accordance with the standards specified in the preceding paragraph. Manufacturing may only commence after passing inspection and obtaining manufacturing approval from the central competent authority. However, product items announced by the central competent authority are exempt from obtaining manufacturing approval.

Foreign manufacturers of imported medical devices shall mutatis mutandis apply the preceding two paragraphs, and the central competent authority may, at regular intervals or as needed, conduct inspections at the foreign manufacturing sites.

The quality management system standards mentioned in Paragraph 1, the inspection content and methods mentioned in Paragraph 2, requirements for approval, procedures, review, issuance, validity period, modifications, revocation or termination, and other compliance matters shall be prescribed by the central competent authority.

[Related Penalty Provisions] Paragraphs 1, 2, 3 ~ §68; Paragraph 4 ~ §70

Article 23

Medical device manufacturers may not entrust nor accept the commission to manufacture medical devices from other manufacturers without approval from the central competent authority.

Medical device distributors may not manufacture medical devices. However, if they are approved by the central competent authority to entrust the manufacture to other medical device manufacturers, this restriction does not apply.

The guidelines for application documents, product liability, contractual provisions, labeling, packaging, and other related operational matters for the commissioned manufacturing mentioned in the preceding two paragraphs shall be prescribed by the central competent authority.

[Related Penalty Provisions] Paragraphs 1, 2 ~ §70

Article 24

Medical devices and their distributors announced by the central competent authority shall establish a Good Distribution Practice (GDP) system for medical devices, to regulate storage, distribution, service, personnel allocation, and other related operational matters for such products, and shall comply with the Good Distribution Practice standards for medical devices.

Medical device distributors shall establish a GDP system for medical devices in accordance with the standards specified in the preceding paragraph and may only wholesale, import, or export after obtaining distribution approval from the central competent authority upon passing inspection.

The Good Distribution Practice standards mentioned in Paragraph 1, the inspection content and methods mentioned in the preceding paragraph, requirements for approval, procedures, review, issuance, validity period, modifications, revocation or termination, and other compliance matters shall be prescribed by the central competent authority.

[Related Penalty Provisions] Paragraphs 1, 2 ~ §70; Paragraph 3 ~ §71

Translated by RegDesk AI

第三章　醫療器材之登錄及查驗登記

第25條

製造、輸入醫療器材，應向中央主管機關申請查驗登記，經核准發給醫療器材許可證後，始得為之。但經中央主管機關公告之品項，其製造、輸入應以登錄方式為之。

醫療器材應依前項規定辦理查驗登記者，不得以登錄方式為之。

醫療器材之輸入，應由許可證所有人、登錄者或其授權者為之。

依第一項但書規定應登錄之醫療器材，於本法施行前已取得醫療器材許可證者，由中央主管機關逕予登錄及註銷原許可證，並通知原許可證所有人。

【相關罰則】第一項、第二項~§62、§68；第一項~§70

第26條

醫療器材查驗登記或登錄之事項，經中央主管機關指定者，其變更應報中央主管機關核准後，始得為之。

【相關罰則】§70

第27條

醫療器材製造、輸入許可證有效期間最長為五年，自發證日起算，期滿仍須繼續製造、輸入者，應事先申請中央主管機關核准展延之；每次展延，不得超過五年。屆期未申請或經否准展延者，原許可證失其效力，並由中央主管機關註銷之。

前項許可證有污損致不堪使用時，應檢附原許可證，申請中央主管機關換發；有遺失時，應申請補發。

第28條

醫療器材商完成醫療器材登錄者，每年應向中央主管機關辦理年度申報；屆期未申報者，原登錄失其效力。依第二十五條第四項規定逕予登錄之醫療器材，亦同。

第29條

下列相關事項之準則，由中央主管機關定之：

一、依第二十五條規定申請醫療器材查驗登記與許可證核發或登錄之條件、程序及審查基準。

二、依第二十六條規定申請變更查驗登記或登錄事項之條件及程序。

三、依第二十七條規定申請許可證展延、換發及補發之程序。

四、依前條規定辦理年度申報之程序。

Chapter 3 Registration and Market Authorization of Medical Devices

Article 25

To manufacture or import medical devices, an application for market authorization shall be submitted to the central competent authority. Only after approval and issuance of the medical device license may such activities be undertaken. However, for items announced by the central competent authority, their manufacture or import shall be conducted by means of registration.

Medical devices required to undergo market authorization pursuant to the preceding paragraph shall not be processed by means of registration.

The importation of medical devices shall be conducted by the license holder, registrant, or their authorized representative.

For medical devices that, in accordance with the proviso of Paragraph 1, are required to be registered and have obtained a medical device license prior to the implementation of this Act, the central competent authority shall directly proceed with their registration and cancel the original license, and notify the original license holder.

[Relevant Penalties] Paragraphs 1 & 2—§62, §68; Paragraph 1—§70

Article 26

For matters specified by the central competent authority regarding the market authorization or registration of medical devices, any changes thereto shall only be made after obtaining the approval of the central competent authority.

[Relevant Penalty] §70

Article 27

The validity period of manufacture or import licenses for medical devices shall be no more than five years, calculated from the date of issuance. Those who still need to continue manufacture or import upon expiry shall apply in advance to the central competent authority for approval of renewal; each renewal shall not exceed five years. If the renewal is not applied for within the prescribed period or is denied, the original license shall become invalid and shall be canceled by the central competent authority.

If the license referred to in the preceding paragraph is damaged and rendered unusable, the original license shall be submitted to the central competent authority for replacement; if lost, an application for reissuance shall be made.

Article 28

Medical device firms that have completed registration of medical devices shall submit an annual report to the central competent authority each year; if the report is not submitted within the prescribed period, the original registration shall become invalid. The same applies to medical devices directly registered in accordance with Article 25, Paragraph 4.

Article 29

The following standards shall be prescribed by the central competent authority:

1. The conditions, procedures, and review criteria for applying for medical device market authorization, license issuance, or registration in accordance with Article 25.

2. The conditions and procedures for applying for changes to matters concerning market authorization or registration in accordance with Article 26.

3. The procedures for applying for license renewal, replacement, or reissuance in accordance with Article 27.

Translated by RegDesk AI

4. The procedures for conducting the annual report as stipulated in the preceding Article.

Translated by RegDesk AI

第30條

經中央主管機關指定品項之醫療器材，應符合特定之規格及性能。

前項醫療器材之品項、規格、檢驗方法及性能，由中央主管機關公告之；未定檢驗方法者，得依國際間認可之方法為之；如未有國際間認可之檢驗方法者，應予以證實其合適性。

第31條

中央主管機關對於醫療器材商辦理查驗登記或登錄時所檢附之資料，屬營業上秘密或經營事業有關之資訊，應限制公開或不予提供。但對公益或保護人體健康有必要者，不在此限。

第32條

醫療器材商製造、輸入醫療器材，應於最小販售包裝標示中文標籤，並附中文說明書，始得買賣、批發及零售。但因窒礙難行，經中央主管機關公告或核准者，不在此限。

【相關罰則】§70

第33條

醫療器材商對醫療器材之標籤、說明書或包裝，應依第十三條第二項及第二十五條第一項之核准、查驗登記或登錄內容，刊載下列事項。但經中央主管機關公告免予刊載者，不在此限：

一、品名。

二、許可證字號或登錄字號。

三、效能、用途或適應症。

四、製造日期及有效期間，或保存期限。

五、型號、規格或主要成分。

六、警告、注意事項、使用限制或預期可預見之副作用。

七、許可證所有人或登錄者之名稱及地址。

八、製造業者名稱及地址。

九、批號或序號。

十、其他經中央主管機關公告應刊載事項。

經中央主管機關公告之特定醫療器材，得以電子化說明書取代前項說明書。

醫療器材除依第一項規定刊載外，有提供點字或其他足供資訊易讀之輔助措施必要者，由中央主管機關公告之。

【相關罰則】§70

Article 30

Medical devices of specific items designated by the central competent authority shall comply with specific specifications and performance requirements.

The items, specifications, testing methods, and performance of the medical devices mentioned in the preceding paragraph shall be announced by the central competent authority; if testing methods have not been determined, internationally recognized methods may be adopted; if no internationally recognized testing methods exist, the suitability of the method used shall be substantiated.

Article 31

The central competent authority shall restrict disclosure or refuse to provide any business secrets or business-related information submitted by medical device firms during the processes of market approval registration or listing. However, this restriction shall not apply if it is necessary for public interest or the protection of human health.

Article 32

Medical device firms, when manufacturing or importing medical devices, shall label the minimum sales package with a Chinese label and attach a Chinese instructions for use, prior to sale, wholesale, or retail. However, if this requirement is impractical and has been publicly announced or approved by the central competent authority, it shall not apply.

[Relevant Penalties] §70

Article 33

Medical device firms shall indicate the following items on the label, instructions for use, or packaging of medical devices, in accordance with the approval or market registration content specified in Article 13, Paragraph 2 and Article 25, Paragraph 1. However, items announced by the central competent authority as exempt from publication may be omitted:

1. Product name.

2. License number or registration number.

3. Performance, intended use or indications.

4. Manufacturing date and period of validity, or expiry date.

5. Model, specifications, or main ingredients.

6. Warnings, precautions, usage restrictions, or foreseeable adverse effects.

7. Name and address of the license holder or registrant.

8. Name and address of the manufacturer.

9. Lot number or serial number.

10. Other items announced by the central competent authority as required for publication.

For specific medical devices announced by the central competent authority, an electronic instructions for use may replace the instructions for use specified in the preceding paragraph.

In addition to the requirements of Paragraph 1, for medical devices for which braille or other auxiliary measures for information readability are necessary, the central competent authority shall announce such requirements.

[Relevant Penalties] §70

Translated by RegDesk AI

第34條

國內製造之醫療器材輸出國外銷售時，其應輸入國家要求證明文件者，製造業者得向中央主管機關申請證明文件。

前項醫療器材，中央主管機關認有不敷國內需求之虞時，得限制其輸出。

經核准製造專供外銷之醫療器材，不得於國內銷售。但中央主管機關認國內有需求之虞時，不在此限。

醫療器材商持有經中央主管機關公告為必要醫療器材之許可證，如有無法繼續製造、輸入或不足供應該醫療器材之虞時，應至少於六個月前向中央主管機關通報；如因天災或其他不應歸責於醫療器材商之事由，而未及於前述期間內通報者，應於事件發生後三十日內向中央主管機關通報。

中央主管機關於接獲前項通報或得知必要醫療器材有不足供應之虞時，得登錄於公開網站。

【相關罰則】第三項~§68

第35條

有下列情形之一者，中央主管機關得專案核准特定醫療器材之製造或輸入，不受第二十五條第一項規定之限制：

一、為預防、診治危及生命或嚴重失能之疾病，國內尚無合適替代療法。

二、因應緊急公共衛生情事之需要。

三、試驗用醫療器材。

四、專供樣品或贈品之用，或個人自用。

五、輸入專供維修，且修復後非於國內流通販賣。

六、依前條第四項公告為必要醫療器材之許可證產品，有無法繼續製造、輸入或不足供應之情形。

前項專案核准之申請條件、審查程序、核准基準、供售限制、退運及其他應遵行事項之辦法，由中央主管機關定之。

【相關罰則】第二項~§70

第36條

前條專案核准製造或輸入之醫療器材，有下列情形之一者，中央主管機關得廢止其核准及令申請者限期處理或回收該醫療器材：

一、已有合適替代療法。

二、緊急公共衛生情事已終結。

三、經中央主管機關評估確有安全或醫療效能之疑慮。

Article 34

When domestically manufactured medical devices are exported for sales abroad and the importing country requires certification documents, the manufacturer may apply to the central competent authority for such certification documents.

Regarding the medical devices mentioned in the preceding paragraph, if the central competent authority determines that there may be a shortage of domestic supply, it may restrict their export.

Medical devices that have been approved for manufacture exclusively for export may not be sold domestically. However, this restriction does not apply if the central competent authority determines that there may be domestic demand.

If a medical device business holds a license for a medical device announced as necessary by the central competent authority and is unable to continue manufacturing, importing, or is at risk of insufficient supply of said medical device, it shall notify the central competent authority at least six months in advance. If, due to natural disasters or other reasons not attributable to the medical device business, notification cannot be made within the aforementioned period, notification shall be made to the central competent authority within thirty days after the occurrence of the event.

Upon receiving the notification in the preceding paragraph or becoming aware that there is a risk of insufficient supply of necessary medical devices, the central competent authority may record it on a public website.

[Relevant Penalty Provisions] Paragraph 3 – §68

Article 35

Under any of the following circumstances, the central competent authority may, by special approval, authorize the manufacture or import of specific medical devices, which shall not be subject to the restrictions of Article 25, Paragraph 1:

1. For the prevention, diagnosis, or treatment of diseases that are life-threatening or cause severe disability, where no suitable alternative therapies exist domestically.

2. To address needs arising from urgent public health incidents.

3. For medical devices intended for testing purposes.

4. Exclusively for use as samples or gifts, or for personal use.

5. Importation exclusively for repair purposes, provided that the restored device will not be distributed or sold domestically.

6. Where a product licensed as a necessary medical device as announced pursuant to Paragraph 4 of the preceding article is unable to continue being manufactured, imported, or is at risk of insufficient supply.

The conditions for application, review procedure, approval criteria, sale restrictions, returns, and other compliance requirements for the special approval in the preceding paragraph shall be prescribed by the central competent authority.

[Relevant Penalty Provisions] Paragraph 2 – §70

Article 36

For medical devices manufactured or imported based on the special approval under the preceding article, if any of the following circumstances occur, the central competent authority may revoke its approval and order the applicant to handle or recall said medical device within a specified period:

1. A suitable alternative therapy already exists.

2. The urgent public health incident has ended.

Translated by RegDesk AI

3. Upon evaluation by the central competent authority, there are confirmed safety or medical efficacy concerns.

Translated by RegDesk AI

第四章　醫療器材臨床試驗之管理

第37條

臨床試驗機構或試驗委託者發起醫療器材臨床試驗，應申請中央主管機關核准後，始得為之。但無顯著風險經中央主管機關公告者，不在此限。

臨床試驗機構執行前項試驗，應善盡醫療上必要之注意，除情況緊急者外，應先取得受試者之同意。

前二項醫療器材臨床試驗之管理範圍、作業規範、申請程序、審查基準、利益迴避、資訊揭露、監督管理、查核、受試者同意書應記載內容及其他應遵行事項之辦法，由中央主管機關定之。

【相關罰則】第一項、第二項~§70；第三項~§71

第38條

醫療器材臨床試驗之受試者，於臨床試驗施行期間發生下列情事之一者，臨床試驗機構及試驗委託者應通報中央主管機關：

一、死亡。

二、危及生命。

三、暫時或永久性失能。

四、受試者之胎兒或嬰兒先天性畸形。

五、需住院或延長住院。

六、其他可能導致永久性傷害之併發症。

臨床試驗終止後，受試者發生前項情事之一，且與臨床試驗有關者，臨床試驗機構應通報中央主管機關。

前二項通報，應於得知事實後七日內為之，並於十五日內檢具詳細調查資料，報中央主管機關備查。

【相關罰則】§71

第39條

中央主管機關認醫療器材臨床試驗有危害人體健康之虞者，得令試驗之機構中止或終止試驗，或採取其他必要之措施。

第五章　醫療器材廣告之管理

第40條

非醫療器材商不得為醫療器材廣告。

【相關罰則】§65

Chapter IV Management of Clinical Trials for Medical Devices

Article 37

When a clinical trial institution or trial sponsor initiates a clinical trial for medical devices, an application for approval must be submitted to the central competent authority before proceeding. However, this does not apply to cases announced by the central competent authority as involving no significant risk.

When a clinical trial institution conducts the aforementioned trial, it shall exercise the necessary medical due diligence and, unless in emergency situations, obtain the informed consent of the subject in advance.

The scope of management, operational guidelines, application procedures, review criteria, conflict of interest avoidance, information disclosure, supervision and management, inspection, required contents of the informed consent form for medical device clinical trials set forth in the preceding two paragraphs, and other matters to be observed, shall be prescribed by the central competent authority.

[Relevant Penalties] Paragraphs 1, 2 ~ §70; Paragraph 3 ~ §71

Article 38

If any of the following circumstances occur to a subject during the implementation period of a medical device clinical trial, the clinical trial institution and the trial sponsor shall notify the central competent authority:

1. Death.

2. Life-threatening situation.

3. Temporary or permanent disability.

4. Congenital malformation of the subject's fetus or infant.

5. Hospitalization or extension of hospitalization required.

6. Other complications that may lead to permanent injury.

If, after termination of the clinical trial, any of the circumstances listed in the preceding paragraph occur to a subject and are related to the clinical trial, the clinical trial institution shall notify the central competent authority.

Notification for the preceding two paragraphs shall be made within seven days after becoming aware of the facts, and detailed investigation materials shall be submitted to the central competent authority for record within fifteen days.

[Relevant Penalties] §71

Article 39

If the central competent authority deems that a clinical trial for medical devices poses a hazard to human health, it may order the institution conducting the trial to suspend or terminate the trial, or take other necessary measures.

Chapter V Management of Medical Device Advertisements

Article 40

No person other than a medical device dealer may advertise medical devices.

[Relevant Penalties] §65

Translated by RegDesk AI

第41條

醫療器材商刊播醫療器材廣告時，應由許可證所有人或登錄者於刊播前，檢具廣告所有文字、圖畫或言詞，依醫療器材商登記所在地，在直轄市者向直轄市主管機關，在縣（市）者向中央主管機關，申請核准刊播；經核准後，應向傳播業者送驗核准文件，始得刊播。

醫療器材廣告於核准刊播期間，不得變更原核准事項而為刊播。

原核准機關發現已核准之醫療器材廣告內容或刊播方式違反前項規定，或對民眾人體健康有危害之虞時，應令醫療器材商立即停止刊播或限期改善；屆期未改善者，廢止其核准。

為前項處分之機關應副知刊播之傳播業者。

【相關罰則】第一項、第二項~§65

第42條

傳播業者不得刊播未經中央或直轄市主管機關核准、與核准事項不符、已廢止或經令立即停止刊播，或限期改善而尚未改善之醫療器材廣告。

接受委託刊播之傳播業者，應自廣告最後刊播日之次日起六個月內，保存委託刊播廣告者之姓名或名稱、身分證明文件或事業登記文件字號、住居所、事務所或營業所、電話及其他相關資料；主管機關要求提供時，傳播業者不得規避、妨礙或拒絕。

【相關罰則】第一項、第二項~§66

第43條

醫療器材廣告核准文件有效期間為三年，自核發證明文件之日起算。期滿有繼續刊播之必要者，應於期滿前六個月內，申請原核准機關展延之；每次展延期間，不得超過三年。

第44條

醫療器材於說明書載明須由醫事人員使用，或經中央主管機關公告者，其廣告以登載於專供醫事人員閱聽之醫療刊物、傳播工具，或專供醫事人員參與之醫療學術性相關活動為限。

【相關罰則】§65

第45條

醫療器材廣告，不得以下列方式為之：

一、假借他人名義為宣傳。

二、利用書刊、文件或資料保證其效能或性能。

三、藉採訪或報導為宣傳。

11

Article 41

When a medical device dealer publishes a medical device advertisement, the holder of the license or the registrant shall, prior to publication, submit all texts, pictures, or verbal content of the advertisement for approval. The application shall be made to the competent authority of the municipality in the case of a municipality, or to the central competent authority in the case of a county (city), based on the registered location of the medical device dealer. Only after approval, and upon submission of the approval documents to the broadcasting entity, may the advertisement be published.

During the approval period of a medical device advertisement, the originally approved items must not be altered for publication.

If the original approving authority finds that the content or the mode of publication of an approved medical device advertisement violates the preceding paragraph, or poses a potential harm to public human health, it shall order the medical device dealer to immediately cease publication or make improvements within a specified period. Failure to make improvements within the period shall result in revocation of the approval.

The authority making the aforementioned disposition shall also notify the broadcasting entity involved in the publication.

[Relevant Penalty Provisions] Paragraphs 1 and 2 ~ §65

Article 42

Broadcasting entities shall not publish medical device advertisements that have not been approved by the central or municipal competent authority, that are inconsistent with the approved items, have been revoked, ordered to cease publication immediately, or ordered to be improved within a specified period but have not yet been improved.

For entrusted advertisements, broadcasting entities shall retain, for six months starting from the day after the final publication date of the advertisement, the name or designation of the entity commissioning the advertisement, identification documents or business registration document number, address, office or place of business, telephone number, and other relevant information. When requested by the competent authority, broadcasting entities must not evade, obstruct, or refuse to provide such information.

[Relevant Penalty Provisions] Paragraphs 1 and 2 ~ §66

Article 43

The validity period of the approval document for a medical device advertisement is three years from the date of issuance. If continued publication is necessary upon expiration, an application for extension must be submitted to the original approving authority within six months before expiration; each extension period must not exceed three years.

Article 44

If the package insert of a medical device specifies that it must be used by medical personnel, or if it is publicly announced by the central competent authority, its advertisements shall be limited to publication in medical journals, media, or tools exclusively for medical personnel or at medical academic-related activities exclusively for medical personnel participation.

[Relevant Penalty Provisions] §65

Article 45

Medical device advertisements must not be made in the following ways:

1. Falsely using another person’s name for promotion.

Translated by RegDesk AI

2. Using books, documents, or materials to guarantee its efficacy or performance.

3. Using interviews or news reports for promotion.

Translated by RegDesk AI

四、以其他不正當方式為宣傳。

【相關罰則】§65

第46條

非醫療器材，不得為醫療效能之標示或宣傳。但其他法律另有規定者，不在此限。

【相關罰則】§65

第六章　監督及預防

第47條

醫療器材經核准製造、輸入或完成登錄者，中央主管機關得指定品項、期間，令醫療器材商依公告或核定之安全監視計畫，監視其安全性；醫事機構應協助提供相關安全監視資料予醫療器材商。

前項醫療器材商應定期製作安全監視報告繳交中央主管機關。未定期繳交安全監視報告或經中央主管機關認該產品有安全疑慮，或安全監視計畫執行之方式、內容與原公告或核定不符者，得令其限期改善或延長監視期間，必要時得令其暫停製造、輸入或販賣；情節重大者，得逕予廢止其許可證或登錄。

前二項安全監視資料及報告，其繳交方式、期限、內容、格式、蒐集資料之限制與維護、監視期間、評估及其他相關事項之辦法，由中央主管機關定之。

第48條

醫療器材商或醫事機構發現醫療器材嚴重不良事件，應通報中央主管機關。

前項嚴重不良事件之情形、通報方式、期限、內容及其他應遵行事項之辦法，由中央主管機關定之。

【相關罰則】第一項、第二項~§70

第49條

醫療器材許可證所有人或登錄者發現醫療器材有危害人體健康之虞時，應即主動通報中央主管機關，並採取矯正預防措施。

前項矯正預防措施，應包括訂定警訊內容、更換零配件、產品檢測、暫停使用、產品回收或其他必要措施，並以合理方式揭露之，供醫事機構、醫療器材商及使用者知悉。

【相關罰則】§71

12

4. Promotion by other improper means.

[Relevant Penalty] §65

Article 46

Non-medical devices shall not be labeled or promoted as having medical efficacy. However, this does not apply if otherwise provided by other laws.

[Relevant Penalty] §65

Chapter 6 Supervision and Prevention

Article 47

For medical devices that have been approved for manufacture, importation, or registration, the central competent authority may designate specific items and periods, and order medical device firms to monitor their safety in accordance with the publicly announced or approved safety surveillance program; medical institutions shall assist in providing relevant safety surveillance data to the medical device firms.

The medical device firms mentioned in the preceding paragraph shall regularly submit safety surveillance reports to the central competent authority. If such reports are not submitted regularly or if the central competent authority determines that there are safety concerns with the product, or the implementation method and content of the safety surveillance program do not comply with the original announcement or approval, the authority may order improvements within a specified period or extend the monitoring period. If necessary, the authority may order suspension of manufacture, importation, or sale; in severe cases, it may revoke the license or registration directly.

The methods, deadlines, content, formats, restrictions on collection, maintenance of surveillance data and reports as referred to in the preceding two paragraphs, as well as the duration of monitoring, assessment, and other related matters, shall be prescribed by the central competent authority.

Article 48

Medical device firms or medical institutions that discover a serious adverse event of a medical device shall report to the central competent authority.

The procedures, methods of reporting, deadlines, content, and other matters to be complied with concerning serious adverse events in the preceding paragraph shall be prescribed by the central competent authority.

[Relevant Penalty] Paragraphs 1 and 2~§70

Article 49

The medical device license holder or registrant who discovers that a medical device may jeopardize human health shall immediately report to the central competent authority and take corrective and preventive measures.

The corrective and preventive measures mentioned in the preceding paragraph shall include determining the content of warnings, replacement of components, product inspection, suspension of use, product recall, or other necessary measures, and shall be disclosed in a reasonable manner for awareness by medical institutions, medical device firms, and users.

[Relevant Penalty] §71

Translated by RegDesk AI

第50條

醫療器材經核准製造、輸入或完成登錄者，於其製造、輸入許可證或登錄有效期間內，經中央主管機關重新評估認有安全或醫療效能疑慮者，得令醫療器材商限期改善，必要時得令其下架、回收、暫停製造、輸入、販賣；屆期未改善或安全疑慮重大者，得廢止其許可證或登錄。

第七章　稽查及取締

第51條

主管機關得派員檢查醫療器材商或醫事機構之處所設施及有關業務，並得抽驗其醫療器材，受檢者不得規避、妨礙或拒絕；其抽驗數量，以足供檢驗之用者為限，並應交付憑據予業者。

【相關罰則】§70

第52條

經中央主管機關指定之醫療器材品項，其輸入時應經抽查、檢驗，合格後始得放行。

前項醫療器材之品項、抽查與檢驗項目、方式、方法、範圍、收費及其他相關事項之辦法，由中央主管機關定之。

第53條

直轄市、縣（市）主管機關應至少每二年辦理醫療器材商普查；醫療器材商不得規避、妨礙或拒絕。

【相關罰則】§71

第54條

中央主管機關發現醫療器材有重大危害人體健康之虞時，應即禁止其製造、輸入，並得廢止其醫療器材許可證或登錄；其已製造或輸入者，應限期禁止其輸出、販賣、供應、運送、寄藏、媒介、轉讓或意圖販賣而陳列；必要時並得沒入銷燬之。

第55條

直轄市、縣（市）主管機關對疑為未經查驗登記、登錄之醫療器材或不良醫療器材，就未經查驗登記、登錄之醫療器材部分，應先行就地封存，並抽取樣品予以查核或檢驗後，再行處理；就不良醫療器材部分，得先行就地封存，並抽取樣品予以查核或檢驗後，再行處理。其已發生重大危害者，應於報請中央主管機關核准後，沒入銷燬之。

前項抽驗數量，以足供查核或檢驗之用者為限，並應交付憑據予業者。

13

Article 50

Where a medical device, for which manufacturing or import has been approved, or registration has been completed, is found within the validity period of its manufacturing, import license, or registration, to have safety or medical efficacy concerns after reassessment by the central competent authority, the medical device dealer may be ordered to make improvements within a specified period. When necessary, the authority may order the device to be removed from shelves, recalled, or suspend its manufacturing, import, or sale. If no improvement is made within the specified period, or if the safety concerns are significant, the license or registration may be revoked.

Chapter 7 Inspection and Enforcement

Article 51

The competent authority may assign personnel to inspect the business premises and related operations of medical device dealers or medical institutions, and may conduct random sampling of their medical devices. The party under inspection shall not evade, obstruct, or refuse such inspection. The sampled quantity shall be limited to that sufficient for inspection purposes, and a receipt shall be issued to the dealer.

[Relevant Penalty Provisions] §70

Article 52

Medical device items designated by the central competent authority shall be subject to random inspection and testing upon importation, and may only be released after passing inspection.

The categories of medical devices in the preceding paragraph, as well as the items, methods, procedures, scope, fees, and other relevant matters concerning random inspection and testing, shall be prescribed by the central competent authority.

Article 53

Municipal or county (city) competent authorities shall conduct a general survey of medical device dealers at least every two years; medical device dealers shall not evade, obstruct, or refuse such survey.

[Relevant Penalty Provisions] §71

Article 54

If the central competent authority discovers that any medical device poses a significant risk to human health, it shall immediately prohibit its manufacture or import and may revoke its medical device license or registration; any devices already manufactured or imported shall be prohibited, within a given period, from being exported, sold, supplied, transported, stored, distributed, transferred, or displayed with intent to sell; when necessary, such devices may be confiscated and destroyed.

Article 55

Where there is suspicion of unregistered medical devices or defective medical devices, the municipal or county (city) competent authority shall, in the case of suspected unregistered medical devices, first seal the items in place and take samples for verification or inspection before further action; in the case of defective medical devices, the authority may likewise first seal the items in place and take samples for verification or inspection before further action. In cases where significant harm has occurred, approval from the central competent authority shall be obtained prior to confiscation and destruction.

The quantity of samples taken in the preceding paragraph shall be limited to that sufficient for verification or inspection, and a receipt shall be issued to the dealer.

Translated by RegDesk AI

第一項醫療器材，主管機關得通知或公告其下架、停止使用，或暫停製造、輸入、販賣。

【相關罰則】第三項~§71

第56條

未經查驗登記、登錄之醫療器材或不良醫療器材，除依本法有關規定處理外，並依其情形分別為下列處分：

一、製造、輸入未經查驗登記或登錄之醫療器材及頂替使用許可證者，原核准機關得廢止其全部或一部醫療器材許可證或登錄、醫療器材商許可執照、醫療器材製造許可，或公司、商業、工廠之登記事項。

二、販賣或意圖販賣而陳列未經查驗登記或登錄之醫療器材者，應禁止其販賣；再次違反者，得令其停止營業。

三、製造、輸入、販賣或意圖販賣而陳列不良醫療器材者，其情節重大或再次違反者，得由原核准機關廢止其各該醫療器材許可證或登錄、醫療器材製造許可或令其停止營業。

主管機關得公布前項受處分公司或商號之名稱、地址、負責人姓名、醫療器材名稱及違反情節。

第57條

查獲之不良醫療器材係本國製造者，經查核或檢驗後仍可改製使用時，應由直轄市、縣（市）主管機關派員監督原製造廠商限期改製；其不能改製或屆期未改製者，沒入銷燬之；國外輸入者，應即封存，並由直轄市、縣（市）主管機關令原進口商限期退運出口，屆期未能退貨者，沒入銷燬之。

查獲第八條第六款之不良醫療器材者，按其情節，應令製造、輸入之該醫療器材商限期改正品質管理系統。

經認定為未經查驗登記或登錄而製造、輸入之醫療器材，準用第一項規定。

【相關罰則】第二項~§71

第58條

醫療器材有下列情形之一者，製造、輸入之醫療器材商應即通知醫事機構、其他醫療器材商及藥局，並依規定期限回收處理市售品及庫存品：

一、原領有許可證或完成登錄，經公告禁止製造或輸入。

二、為不良醫療器材或未經查驗登記或登錄。

三、經檢查、檢驗或其他風險評估，發現有危害使用者人體健康之虞。

四、醫療器材製造許可經中央主管機關廢止或非於醫療器材製造許可有效期

14

For Class I medical devices, the competent authority may notify or announce their withdrawal from shelves, suspension of use, or temporary suspension of manufacture, import, or sale.

[Relevant Penalties] Paragraph 3 ~ §71

Article 56

Medical devices that have not undergone registration for inspection, have not been listed, or are deemed defective, in addition to being handled according to the relevant provisions of this Act, shall also be subject to the following dispositions based on the circumstances:

1. Manufacturers or importers of medical devices that have not undergone registration for inspection or listing, or who use substitute licenses, may have all or part of their medical device licenses or registrations, medical device business licenses, medical device manufacturing permits, or the registration details of their company, business, or factory revoked by the original approving authority.

2. Those selling, or displaying for sale with intent to sell, medical devices that have not undergone registration for inspection or listing, shall be prohibited from selling such devices; for repeated violations, they may be ordered to suspend business operations.

3. Those manufacturing, importing, selling, or displaying for sale with intent to sell, defective medical devices, where the circumstances are serious or there is a repeat violation, may have all or part of their medical device licenses or registrations, medical device manufacturing permits revoked, or may be ordered to suspend business operations by the original approving authority.

The competent authority may announce the name, address, responsible person, names of medical devices, and the circumstances of violation of the companies or businesses receiving dispositions under the preceding paragraph.

Article 57

If defective medical devices found are manufactured domestically, and after inspection or examination are still suitable for modification and use, the municipal or county (city) competent authority shall dispatch personnel to supervise the original manufacturer to modify them within a set period; if they cannot be modified, or are not modified within the period, they shall be confiscated and destroyed. For imported defective medical devices, they shall be immediately sealed and the municipal or county (city) competent authority shall order the original importer to re-export the products within a set period; if the deadline is not met, the products shall be confiscated and destroyed.

If defective medical devices as described in Subparagraph 6 of Article 8 are found, depending on the circumstances, the manufacturer or importer of the medical device shall be ordered to rectify the quality management system within a set period.

Medical devices determined to have been manufactured or imported without registration for inspection or listing shall be handled in accordance with Paragraph 1 herein.

[Relevant Penalties] Paragraph 2 ~ §71

Article 58

Where any of the following circumstances apply to a medical device, the manufacturer or importer shall immediately notify medical institutions, other medical device businesses, and pharmacies, and recall and handle both products on the market and those in inventory within the time limit specified by regulation:

1. A device for which a license was originally obtained or registration was completed, but whose manufacture or import has been prohibited by public announcement.

Translated by RegDesk AI

2. The device is defective or has not undergone registration for inspection or listing.

3. During inspection, examination, or other risk assessment, it is found that there is a possible risk to the health of users.

4. The medical device manufacturing permit has been revoked by the central competent authority, or is not within the period of validity of the medical device manufacturing permit.

Translated by RegDesk AI

間內製造或輸入。

五、製造、輸入醫療器材違反第二十六條、第三十二條或第三十三條規定。

六、其他經中央主管機關公告應回收。

製造、輸入之醫療器材商回收前項醫療器材時，醫事機構、其他醫療器材商及藥局應予配合。

第一項應回收之醫療器材，其分級、回收作業方式、處理方法及其他應遵行事項之辦法，由中央主管機關定之。

【相關罰則】第一項第一款至第三款~§65；第一項第四款至第六款、第二項、第三項~§71

第59條

主管機關對於檢舉查獲不良醫療器材或未經查驗登記或登錄之醫療器材者，除應對檢舉人身分資料嚴守秘密外，並得酌予獎勵。

第八章　罰則

第60條

製造或輸入第八條第一款之不良醫療器材者，處五年以下有期徒刑、拘役或科或併科新臺幣五千萬元以下罰金。

明知為前項之不良醫療器材，而販賣、供應、運送、寄藏、媒介、轉讓或意圖販賣而陳列者，處三年以下有期徒刑、拘役或科或併科新臺幣一千萬元以下罰金。

因過失犯第一項之罪者，處三年以下有期徒刑、拘役或科或併科新臺幣一千萬元以下罰金。

因過失犯第二項之罪者，處拘役或科新臺幣一百萬元以下罰金。

第61條

擅用或冒用本人或他人合法醫療器材之名稱、說明書或標籤者，處五年以下有期徒刑、拘役或科或併科新臺幣二千萬元以下罰金。

明知為前項之醫療器材而輸入、販賣、供應、運送、寄藏、媒介、轉讓或意圖販賣而陳列者，處二年以下有期徒刑、拘役或科或併科新臺幣一千萬元以下罰金。

第62條

意圖販賣、供應而違反第二十五條第一項規定，未經核准擅自製造或輸入醫療器材，或違反第二十五條第二項規定，應辦理查驗登記而以登錄方式為之者，處三年以下有期徒刑、拘役或科或併科新臺幣一千萬元以下罰金。

15

Manufactured or imported within the period.

5. Manufacturing or importing medical devices in violation of Article 26, Article 32, or Article 33.

6. Other circumstances announced as subject to recall by the central competent authority.

When a manufacturer or importer of medical devices recalls the aforementioned medical devices, medical institutions, other medical device businesses, and pharmacies shall cooperate.

The classification of medical devices subject to recall under Paragraph 1, the recall operation procedures, processing methods, and other compliance matters shall be stipulated by the central competent authority.

[Relevant Penalties] Subparagraphs 1 to 3 of Paragraph 1—§65; Subparagraphs 4 to 6, Paragraph 2, Paragraph 3—§71

Article 59

When the competent authority discovers, through reports, substandard medical devices or medical devices that have not been registered or listed as required, it shall keep the identity of the informant strictly confidential and may grant rewards at its discretion.

Chapter Eight: Penalties

Article 60

Any person who manufactures or imports substandard medical devices as described in Article 8, Subparagraph 1, shall be sentenced to imprisonment for not more than five years, short-term detention, or a fine of not more than NT$50 million, or both.

Anyone who knowingly sells, supplies, transports, stores, brokers, transfers, or displays for the purpose of sale such substandard medical devices as specified in the preceding paragraph shall be sentenced to imprisonment for not more than three years, short-term detention, or a fine of not more than NT$10 million, or both.

Anyone who commits the offense specified in Paragraph 1 by negligence shall be sentenced to imprisonment for not more than three years, short-term detention, or a fine of not more than NT$10 million, or both.

Anyone who commits the offense specified in Paragraph 2 by negligence shall be sentenced to short-term detention or a fine of not more than NT$1 million.

Article 61

Any person who illegally uses or fraudulently uses the name, instructions, or labels of their own or another’s legally registered medical device shall be sentenced to imprisonment for not more than five years, short-term detention, or a fine of not more than NT$20 million, or both.

Anyone who knowingly imports, sells, supplies, transports, stores, brokers, transfers, or displays for sale the medical devices specified in the preceding paragraph shall be sentenced to imprisonment for not more than two years, short-term detention, or a fine of not more than NT$10 million, or both.

Article 62

Any person who, with the intent to sell or supply, violates the provisions of Article 25, Paragraph 1, by manufacturing or importing medical devices without approval, or violates the provisions of Article 25, Paragraph 2, by registering such devices through listing instead of required product registration, shall be sentenced to imprisonment for not more than three years, short-term detention, or a fine of not more than NT$10 million, or both.

Translated by RegDesk AI

明知為前項之醫療器材而販賣、供應、運送、寄藏、媒介、轉讓或意圖販賣而陳列者，亦同。

第63條

法人之代表人，法人或自然人之代理人、受雇人或其他從業人員，因執行業務，犯第六十條至前條之罪者，除依各該條規定處罰其行為人外，對該法人或自然人亦科以各該條十倍以下之罰金。

第64條

製造或輸入第八條第二款至第五款、第七款之不良醫療器材者，處新臺幣六萬元以上五千萬元以下罰鍰。

販賣、供應、運送、寄藏、媒介、轉讓或意圖販賣而陳列前項之不良醫療器材者，處新臺幣三萬元以上二千萬元以下罰鍰。

第65條

違反第四十六條規定，非醫療器材為醫療效能之標示或宣傳者，處新臺幣六十萬元以上二千五百萬元以下罰鍰。

有下列情形之一者，處新臺幣二十萬元以上五百萬元以下罰鍰：

一、違反第四十條規定，非醫療器材商為醫療器材廣告。

二、違反第四十一條第一項規定，醫療器材廣告未於刊播前申請核准或向傳播業者送驗核准文件。

三、違反第四十一條第二項規定，醫療器材廣告未經核准擅自變更原核准事項。

四、違反第四十四條所定醫療器材廣告登載範圍之限制。

五、醫療器材廣告方式，有第四十五條規定情形之一。

六、有第五十八條第一項第一款至第三款情形之一，未為通知或未依規定期限回收醫療器材。

第66條

傳播業者違反第四十二條第一項規定刊播廣告者，處新臺幣二十萬元以上五百萬元以下罰鍰，並令其停播；未停播者，按次處罰至其停播為止。

傳播業者未依第四十二條第二項規定保存委託刊播廣告者資料，或規避、妨礙或拒絕主管機關要求提供資料者，處新臺幣六萬元以上三十萬元以下罰鍰，並應按次處罰。

直轄市、縣（市）主管機關為第一項處分時，應通知傳播業者之地方主管機關或目的事業主管機關依相關法令處理。

16

Anyone who, knowing that a medical device is as described in the preceding paragraph, sells, supplies, transports, stores, acts as an intermediary, transfers, or displays with the intent to sell such devices shall be subject to the same provisions.

Article 63

Where the representative of a juristic person, or an agent, employee, or other staff member of a juristic person or natural person, in the course of performing business, commits an offense prescribed from Article 60 to the preceding article, not only shall the perpetrator be punished in accordance with each respective article, but the juristic person or natural person shall also be subject to a fine of up to ten times the fine specified in each of those articles.

Article 64

Anyone manufacturing or importing substandard medical devices as specified in Subparagraphs 2 to 5 and 7 of Article 8 shall be fined not less than NT$60,000 and not more than NT$50,000,000.

Anyone selling, supplying, transporting, storing, acting as an intermediary, transferring, or displaying with the intent to sell the substandard medical devices described in the preceding paragraph, shall be fined not less than NT$30,000 and not more than NT$20,000,000.

Article 65

Anyone who violates Article 46 by labeling or advertising non-medical devices as having medical efficacy shall be fined not less than NT$600,000 and not more than NT$25,000,000.

Any of the following circumstances shall be subject to a fine of not less than NT$200,000 and not more than NT$5,000,000:

1. Violation of Article 40 by a non-medical device business running an advertisement for a medical device.

2. Violation of Paragraph 1, Article 41 by running a medical device advertisement before applying for and obtaining approval, or by failing to submit the approval documents to the media operator.

3. Violation of Paragraph 2, Article 41 by arbitrarily altering approved matters in a medical device advertisement without prior approval.

4. Violation of the restriction on the scope of content of medical device advertisements as stipulated in Article 44.

5. Use of any advertising method for medical devices as described in any subparagraph of Article 45.

6. Occurrence of any circumstance listed in Subparagraphs 1 to 3, Paragraph 1, Article 58, for which notification was not made or the medical device was not recalled within the prescribed period.

Article 66

Any media operator who violates Paragraph 1, Article 42 by broadcasting or publishing advertisements shall be fined not less than NT$200,000 and not more than NT$5,000,000, and shall be ordered to cease broadcast; failure to cease broadcast shall be penalized on a per-instance basis until broadcasting ceases.

Any media operator who fails to retain information on commissioned advertisements as required by Paragraph 2, Article 42, or who evades, obstructs, or refuses the competent authority's request to provide documentation, shall be fined not less than NT$60,000 and not more than NT$300,000, and shall be fined on a per-instance basis.

When a municipality or county (city) competent authority imposes a disposition pursuant to Paragraph 1, it shall notify the local competent authority or the competent authority of the business concerned to handle the matter in accordance with relevant regulations.

Translated by RegDesk AI

第67條

違反第五章規定，除依本章規定處分，並得公布其名稱或姓名、醫療器材名稱及所犯情節外，應視其情節分別為下列處分：

一、廢止該醫療器材許可證或登錄；其原品名二年內不得申請使用。

二、令於處分書送達三十日內，於原刊播之同一篇幅、時段刊播一定次數之更正廣告；其內容應載明表達歉意及排除錯誤訊息。未刊播更正廣告者，處新臺幣十二萬元以上六十萬元以下罰鍰，同時廢止該業者之全部醫療器材廣告核准，並二年內不再受理其廣告之申請。

依前項規定處分後再次違反者，並得令其歇業及廢止其公司、商業、工廠登記之全部或一部登記事項。

第68條

有下列情形之一者，處新臺幣六萬元以上二百萬元以下罰鍰：

一、違反第十七條規定，購入或承租未經查驗登記、登錄或非醫療器材商供應之醫療器材。

二、違反第二十條第一項規定，未符合醫療器材製造業者設置標準。

三、國內醫療器材製造業者，違反第二十二條第一項規定，未符合醫療器材品質管理系統準則，或違反第二十二條第二項規定，未取得製造許可擅自製造醫療器材。

四、醫療器材販賣業者輸入違反第二十二條第三項準用第一項或第二項規定所製造之醫療器材。

五、違反第二十五條第一項規定，製造、輸入醫療器材未辦理查驗登記或登錄，或違反第二十五條第二項規定，應辦理查驗登記而以登錄方式為之。

六、違反第三十四條第三項規定，將專供外銷之醫療器材於國內銷售。

有前項第三款或第四款情形者，除依前項規定處罰外，中央主管機關得公布醫療器材商名稱，並令其限期改善，改善期間得停止其全部或一部醫療器材之製造、輸入或營業；屆期未改善者，不得依第二十七條規定展延醫療器材許可證，或依第二十八條規定辦理年度申報，且不受理該製造業者其他醫療器材查驗登記或登錄之新申請案；其情節重大者，並得廢止其全部或一部之醫療器材製造許可、許可證或登錄。

第69條

醫療器材商使用虛偽不實之文件或資料，辦理本法規定之各項申請者，處新臺幣六萬元以上二百萬元以下罰鍰；情節重大者，二年內不得再申請；其經

Article 67

Violation of the provisions of Chapter 5, in addition to being disposed of in accordance with the regulations of this Chapter, may also have the name or full name, the name of the medical device and the facts of the violation made public. Depending on the circumstances, the following dispositions shall be imposed:

1. The medical device license or registration shall be revoked; the original product name may not be applied for within two years.

2. Order a corrective advertisement of a certain number of times within the same space or time slot as the original publication or broadcast, within thirty days after the disposition is delivered; the content shall express an apology and clarify the erroneous information. If the corrective advertisement is not published or broadcast, a fine of not less than NT$120,000 and not more than NT$600,000 shall be imposed, and all advertising approvals for medical devices of the business shall be revoked, and no applications for advertisements from the business shall be accepted within two years.

If there is a repeated violation after being disposed of in accordance with the preceding paragraph, the business may be ordered to suspend operation and all or part of its company, commercial, or factory registration items may be canceled.

Article 68

Any of the following circumstances shall be subject to a fine of not less than NT$60,000 and not more than NT$2,000,000:

1. Violation of Article 17 by purchasing or leasing medical devices that have not been inspected and registered, recorded, or supplied by medical device dealers.

2. Violation of Paragraph 1, Article 20, by failing to comply with the establishment standards for medical device manufacturers.

3. Domestic medical device manufacturers violating Paragraph 1, Article 22, by failing to comply with the Medical Device Quality Management System Standards, or violating Paragraph 2, Article 22, by manufacturing medical devices without obtaining a manufacturing permit.

4. Medical device dealers importing medical devices in violation of the provisions of Paragraph 3, Article 22, as applied mutatis mutandis to Paragraphs 1 or 2 of Article 22.

5. Violation of Paragraph 1, Article 25, by manufacturing or importing medical devices without inspection registration or recording, or violation of Paragraph 2, Article 25, by handling recording instead of required inspection registration.

6. Violation of Paragraph 3, Article 34, by selling medical devices domestically that are exclusively for export.

Where any of the circumstances in Subparagraph 3 or 4 of the preceding paragraph apply, in addition to the preceding punishments, the central competent authority may make public the name of the medical device dealer and order rectification within a specified period, during which the manufacture, import, or operation of all or part of the medical devices may be suspended. If rectification is not made by the deadline, extension of the medical device license pursuant to Article 27 shall not be permitted, or annual reporting pursuant to Article 28 may not be handled, and new applications for inspection registration or recording of other medical devices by the manufacturer will not be accepted; in cases of serious circumstances, some or all manufacturing permits, licenses, or registrations of medical devices may be revoked.

Article 69

Translated by RegDesk AI

If a medical device dealer uses false or untrue documents or information to apply for various items under this Act, a fine of not less than NT$60,000 and not more than NT$2,000,000 shall be imposed; in serious cases, reapplication shall not be allowed within two years; if

Translated by RegDesk AI

許可或核准者，撤銷之。

第70條

有下列情形之一者，處新臺幣三萬元以上一百萬元以下罰鍰：

一、違反第十三條第一項規定，非為醫療器材商而為醫療器材商之業務，或違反第十三條第二項規定，登記事項變更未辦理變更登記。

二、違反第十三條第三項規定，未辦理醫療器材商登記，或未於登記處所製造、販賣或供應醫療器材。

三、違反依第十八條所為公告之限制規定。

四、違反依第二十二條第四項所定辦法有關變更之規定。

五、違反第二十三條第一項規定，未經核准而委託或接受委託製造醫療器材，或違反第二十三條第二項規定製造醫療器材。

六、違反第二十四條第一項規定，未符合醫療器材優良運銷準則，或違反第二十四條第二項規定，未取得運銷許可擅自批發、輸入或輸出醫療器材。

七、販賣、供應、運送、寄藏、媒介、轉讓或意圖販賣而陳列未依第二十五條第一項規定，辦理查驗登記或登錄之醫療器材。

八、違反第二十六條規定，未經核准擅自變更原查驗登記或登錄事項。

九、違反第三十二條或第三十三條關於醫療器材包裝標示、標籤、說明書或其刊載事項之規定。

十、違反依第三十五條第二項所定辦法有關供售限制或退運之規定。

十一、違反第三十七條第一項規定，未經核准擅自執行臨床試驗，或違反第三十七條第二項規定，執行臨床試驗未先取得受試者之同意。

十二、違反第四十八條第一項規定，未通報中央主管機關，或違反依第四十八條第二項所定辦法有關通報方式、期限、內容之規定。

十三、違反第五十一條規定，規避、妨礙或拒絕檢查或抽驗。

有前項第六款情形者，除依前項規定處罰外，中央主管機關得公布醫療器材商名稱，並令其限期改善，改善期間得停止其全部或一部醫療器材之批發、零售、輸入及輸出；屆期未改善者，得按次處罰至改善為止。

第71條

有下列情形之一者，處新臺幣二萬元以上五十萬元以下罰鍰：

一、製造或輸入第八條第六款之不良醫療器材，情節重大，或經主管機關依第五十七條第二項令其限期改正，屆期未改正。

二、違反第十五條第一項規定，未聘僱技術人員。

18

Those who have obtained permission or approval, shall have such permission or approval revoked.

Article 70

Anyone who commits any of the following acts shall be fined between NT$30,000 and NT$1,000,000:

1. Violating Paragraph 1 of Article 13 by engaging in the business of a medical device dealer without being a medical device dealer, or violating Paragraph 2 of Article 13 by failing to process an amendment registration when changes are made to registered items.

2. Violating Paragraph 3 of Article 13 by failing to register as a medical device dealer, or by failing to manufacture, sell, or supply medical devices at the registered place.

3. Violating the restriction provisions announced in accordance with Article 18.

4. Violating the regulations regarding changes as stipulated by the regulations enacted pursuant to Paragraph 4 of Article 22.

5. Violating Paragraph 1 of Article 23 by commissioning or accepting the commission to manufacture medical devices without approval, or violating Paragraph 2 of Article 23 in the manufacturing of medical devices.

6. Violating Paragraph 1 of Article 24 by failing to conform to the Good Distribution Practices for medical devices, or violating Paragraph 2 of Article 24 by engaging in wholesale, import, or export of medical devices without obtaining a distribution permit.

7. Selling, supplying, transporting, storing by mail, mediating, transferring, or displaying with intent to sell medical devices that have not undergone inspection registration or notification in accordance with Paragraph 1 of Article 25.

8. Violating Article 26 by changing the original inspection registration or notification items without approval.

9. Violating Article 32 or Article 33 regarding packaging labels, labeling, instruction manuals, or the publication of their contents for medical devices.

10. Violating the supply restriction or return regulations enacted according to Paragraph 2 of Article 35.

11. Violating Paragraph 1 of Article 37 by carrying out clinical trials without approval, or violating Paragraph 2 of Article 37 by conducting clinical trials without first obtaining the consent of the subjects.

12. Violating Paragraph 1 of Article 48 by failing to notify the central competent authority, or violating the method, deadline, or content of notification stipulated by regulations enacted according to Paragraph 2 of Article 48.

13. Violating Article 51 by evading, obstructing, or refusing inspection or sampling.

For those who commit an act specified in Subparagraph 6 of the preceding paragraph, in addition to being fined in accordance with the preceding paragraph, the central competent authority may make public the name of the medical device dealer and order rectification within a specified period. During the rectification period, all or part of the medical device dealer’s wholesale, retail, import, and export business may be suspended; if rectification is not made within the period, penalties may be imposed repeatedly until rectification is made.

Article 71

Anyone who commits any of the following acts shall be fined between NT$20,000 and NT$500,000:

Translated by RegDesk AI

1. Manufacturing or importing defective medical devices specified in Subparagraph 6, Article 8, with serious circumstances, or failing to make corrections within the specified period after being ordered to do so by the competent authority pursuant to Paragraph 2 of Article 57.

2. Violating Paragraph 1 of Article 15 by failing to employ technical personnel.

Translated by RegDesk AI

三、違反第十九條第一項、第二項規定，或違反依第十九條第三項所定辦法有關資料之範圍、建立或保存方式、保存年限、申報內容、方式之規定。

四、違反依第二十四條第三項所定辦法有關變更之規定。

五、違反依第三十七條第三項所定辦法有關利益迴避、資訊揭露、監督管理或查核之規定，或經主管機關依該辦法之規定令其限期改善而屆期未改善。

六、違反第三十八條規定，未通報或報備查，或未於期限內通報或報備查。

七、違反第四十九條規定，未通報，或未依規定採取矯正預防措施。

八、違反第五十三條規定，規避、妨礙或拒絕普查。

九、違反第五十五條第三項規定，未下架，或暫停製造、輸入或販賣。

十、有第五十八條第一項第四款至第六款情形之一，未為通知或未依規定期限回收醫療器材。

十一、違反第五十八條第二項規定，未配合回收醫療器材。

十二、違反依第五十八條第三項所定辦法有關醫療器材回收作業方式、處理方法之規定。

第72條

依本法規定處罰鍰，受處分人不服時，得於處分書送達後十五日內，以書面提出異議，申請復核。但以一次為限。

處罰鍰機關應於接到前項異議書後十五日內完成復核，認為有理由者，應變更或撤銷原處分。

受處分人不服前項復核時，得依法提起訴願及行政訴訟。

第73條

依本法申請執行醫療器材臨床試驗、醫療器材查驗登記、許可證變更或展延，未獲核准，申請人不服者，應自處分書送達之日起四個月內，敘明理由提出申復。但以一次為限。

中央主管機關對前項申復認有理由者，應變更或撤銷原處分。

申復人不服申復決定者，得依法提起訴願及行政訴訟。

第74條

本法所定之處分，除另有規定外，由直轄市、縣（市）主管機關為之，必要時得由中央主管機關為之。但有關公司、商業或工廠之全部或一部登記事項之廢止，由直轄市、縣（市）主管機關於勒令歇業處分確定後，移由其工、商業主管機關或其目的事業主管機關為之。

3. Violation of the provisions of Article 19, Paragraphs 1 or 2, or violation of the provisions regarding the scope of data, methods for establishment or preservation, duration of preservation, declaration content, and methods as stipulated pursuant to Article 19, Paragraph 3.

4. Violation of the provisions regarding changes as stipulated pursuant to the regulations enacted in accordance with Article 24, Paragraph 3.

5. Violation of the regulations regarding conflict of interest avoidance, information disclosure, supervision and management, or audit as stipulated pursuant to Article 37, Paragraph 3, or failure to make improvements within the time limit after being ordered to do so by the competent authority in accordance with such regulations.

6. Violation of Article 38 by failing to report or file for review, or failing to report or file for review within the prescribed time limit.

7. Violation of Article 49 by failing to report or failing to take corrective or preventive measures in accordance with regulations.

8. Violation of Article 53 by evading, obstructing, or refusing the census.

9. Violation of Article 55, Paragraph 3 by failing to recall, or failing to suspend manufacturing, import, or sale.

10. Any situation provided under Article 58, Paragraph 1, Subparagraphs 4 to 6, where notification is not given or medical devices are not recalled within the prescribed time limit.

11. Violation of Article 58, Paragraph 2 by failing to cooperate in the recall of medical devices.

12. Violation of the provisions regarding the procedures or methods for recalling medical devices as stipulated pursuant to Article 58, Paragraph 3.

Article 72

Where a fine is imposed under this Act, a person subject to such disposition may, within fifteen days after receipt of the disposition notice, file a written objection requesting a review. However, this may be done only once.

The authority imposing the fine shall complete the review within fifteen days upon receipt of the written objection; if it finds the objection justified, it shall alter or revoke the original disposition.

A person dissatisfied with the result of the preceding review may file an appeal and administrative litigation in accordance with the law.

Article 73

Where an application is made under this Act for the execution of a medical device clinical trial, medical device inspection registration, license amendment, or extension, and the approval is not granted, an applicant who is dissatisfied may, within four months from the date of receipt of the disposition notice, state the reasons and file a petition for redress. However, this may be done only once.

If the central competent authority finds the petition for redress justified, it shall alter or revoke the original disposition.

A petitioner dissatisfied with the decision regarding the petition for redress may file an appeal and administrative litigation in accordance with the law.

Article 74

Translated by RegDesk AI

Unless otherwise provided, the dispositions stipulated in this Act shall be made by the municipal or county (city) competent authority; if necessary, the central competent authority may make such dispositions. However, in cases involving the revocation of all or part of the registration items of a company, business, or factory, after the order to cease business becomes final, such revocation shall be transferred by the municipal or county (city) competent authority to the competent authority for industry and commerce or to the competent authority responsible for the business concerned for processing.

Translated by RegDesk AI

第九章　附則

第75條

依本法執行沒入銷燬所需之必要費用，由受處分人負擔之。

第76條

依本法所為證照或其他事項之申請、申報，或函詢醫療器材產品查驗登記、登錄及年度申報等相關規定，應繳納費用。

前項應繳費用種類及其費額之標準，由中央主管機關定之。

第77條

各級主管機關於必要時，得將醫療器材檢驗之全部或一部，委任所屬機關（構）或委託相關機關（構）、法人或團體辦理；其委任、委託及其相關事項之辦法，由中央主管機關定之。

第78條

中央主管機關得就前條受託檢驗之法人、團體，辦理認證；其認證及管理辦法，由中央主管機關定之。

前項認證工作，得委任所屬機關（構）或委託其他機關（構）、法人或團體辦理；其委任、委託及其相關事項之辦法，由中央主管機關定之。

第79條

本法關於技術人員之教育訓練、醫療器材之查驗登記審查、證明文件之核發、臨床試驗審查及查核、廣告審查、嚴重不良事件通報、醫療器材商檢查或普查等事項，主管機關得委任所屬機關（構），或委託其他機關（構）或經認證之法人或團體辦理。

前項委任或委託事項，除教育訓練外，受託者應遵守利益迴避原則；其委託、認證、利益迴避及其他相關事項之辦法，由中央主管機關定之。

第一項認證工作得委任所屬機關（構）或委託其他機關（構）辦理；其委任、委託及其相關事項之辦法，由中央主管機關定之。

第80條

醫療器材創新科技之研究發展，得由中央主管機關會同中央工業主管機關獎勵之。

前項獎勵之資格條件、審議程序及其他相關事項之辦法，得由中央主管機關會同中央工業主管機關定之。

Chapter 9 Supplementary Provisions

Article 75

The necessary expenses required for the confiscation and destruction executed in accordance with this Act shall be borne by the person subject to disposition.

Article 76

Applications or declarations for permits, licenses, or other matters in accordance with this Act, or inquiries concerning medical device product inspection and registration, listing, and annual declaration, and other relevant regulations, shall require payment of fees.

The types of fees to be paid as referred to in the preceding paragraph and the standards for their amounts shall be determined by the central competent authority.

Article 77

When necessary, competent authorities at all levels may delegate all or part of the inspection of medical devices to their subordinate agencies (institutions) or entrust relevant agencies (institutions), legal persons, or groups to handle them; the regulations governing such delegation, entrustment, and related matters shall be stipulated by the central competent authority.

Article 78

The central competent authority may certify the legal persons or groups entrusted to conduct inspections pursuant to the preceding article; the regulations governing such certification and management shall be formulated by the central competent authority.

The certification work described in the preceding paragraph may be delegated to subordinate agencies (institutions) or entrusted to other agencies (institutions), legal persons, or groups for implementation; the regulations for such delegation, entrustment, and related matters shall be stipulated by the central competent authority.

Article 79

For matters such as the education and training of technical personnel, inspection and registration review of medical devices, issuance of supporting documents, clinical trial review and verification, advertisement review, severe adverse event reporting, and medical device business inspection or census under this Act, the competent authority may delegate to its subordinate agencies (institutions), or entrust to other agencies (institutions) or certified legal persons or groups for implementation.

Except for education and training, the entrusted parties for the delegated or entrusted matters in the preceding paragraph shall comply with the conflict of interest avoidance principle; the methods for entrustment, certification, conflict of interest avoidance, and other related matters shall be determined by the central competent authority.

Certification work referred to in Paragraph 1 may be delegated to subordinate agencies (institutions) or entrusted to other agencies (institutions) for implementation; the regulations for such delegation, entrustment, and related matters shall be stipulated by the central competent authority.

Article 80

The research and development of innovative technologies in medical devices may be awarded by the central competent authority in conjunction with the central industrial competent authority.

The regulations regarding the qualification requirements, review procedures, and other related matters for such awards as referred to in the preceding paragraph may be stipulated by the central competent authority in conjunction with the central industrial competent authority.

Translated by RegDesk AI

第81條

研究機構、醫事機構或醫療器材商，因醫療器材之使用特性，依據個人資料保護法第六條第一項第六款蒐集、處理或利用個人資訊者，中央主管機關得公告其他等同書面之同意方式。

第82條

醫療器材製造、輸入業者違反第八條第一款、第二款規定，致生損害於醫療器材最終使用之病患或消費者時，應負賠償責任。但醫療器材製造、輸入業者證明對於醫療器材之製造、包裝、貼標、滅菌、最終驗放、設計並無欠缺，或其損害非因該項欠缺所致，或於防止損害之發生已盡相當之注意者，不在此限。

前項情形之醫療器材最終使用之病患或消費者，雖非財產上之損害，亦得請求賠償相當之金額。

醫療器材最終使用之病患或消費者因前二項損害之請求，得準用消費者保護法第四十七條至第五十五條之規定提起消費訴訟。

依第一項、第二項情形，如醫療器材最終使用之病患或消費者不易或不能證明其實際損害額時，得請求法院依其受害情節，以每人每一事件新臺幣一千元以上計算。

直轄市、縣（市）政府受理同一原因事件，致二十人以上醫療器材最終使用之病患或消費者受有損害之申訴時，應協助醫療器材最終使用之病患或消費者依消費者保護法第五十條之規定辦理。

第83條

自本法施行之日起，醫療器材之管理，應適用本法之規定，藥事法有關醫療器材之規定，不再適用。

第84條

本法施行細則，由中央主管機關定之。

第85條

本法施行日期，由行政院定之。

21

Article 81

Research institutions, medical institutions, or medical device companies, due to the usage characteristics of medical devices and in accordance with Article 6, Paragraph 1, Subparagraph 6 of the Personal Data Protection Act, when collecting, processing, or using personal information, the central competent authority may announce other consent methods equivalent to written consent.

Article 82

Where a medical device manufacturer or importer violates the provisions of Article 8, Subparagraph 1 or 2, resulting in damages to the patient or consumer who is the ultimate user of the medical device, the manufacturer or importer shall be liable for compensation. However, this shall not apply if the medical device manufacturer or importer can prove that there was no deficiency in the manufacture, packaging, labeling, sterilization, final release, or design of the medical device, or that the damage was not caused by such deficiency, or that reasonable care had been undertaken to prevent the occurrence of the damage.

In the circumstance referred to in the preceding paragraph, the patient or consumer who is the ultimate user of the medical device may also claim for reasonable compensation even if the damage is not pecuniary.

For claims arising from damage as stated in the preceding two paragraphs, the patients or consumers who are the ultimate users of medical devices may initiate consumer litigation in accordance with the provisions of Articles 47 to 55 of the Consumer Protection Act.

In situations as set forth in paragraphs 1 and 2, if the patient or consumer who is the ultimate user of the medical device finds it difficult or impossible to prove the actual amount of damage, they may request the court to determine the amount based on the circumstances of the case, calculated at not less than NT$1,000 per person per incident.

If a municipality or county (city) government receives complaints arising from the same cause involving damage to twenty or more patients or consumers who are the ultimate users of medical devices, it shall assist such patients or consumers to process the matter in accordance with Article 50 of the Consumer Protection Act.

Article 83

From the date of enforcement of this Act, the management of medical devices shall be governed by the provisions of this Act, and the provisions of the Pharmaceutical Affairs Act regarding medical devices shall no longer apply.

Article 84

The enforcement rules of this Act shall be prescribed by the central competent authority.

Article 85

The enforcement date of this Act shall be determined by the Executive Yuan.

Translated by RegDesk AI

【醫療器材管理法施行細則】(110.04.26發布)

第1條

本細則依醫療器材管理法（以下簡稱本法）第八十四條規定訂定之。

第2條

有下列各款情形之一者，不屬本法第六條所定醫療器材廣告：

一、僅刊登醫療器材品名、價格、特價優惠折扣、規格、材質、產品外觀圖片、廠商名稱、地址或電話，未涉及宣傳醫療效能。

二、針對特殊事件之聲明啟事，未涉及宣傳醫療效能。

三、辨別醫療器材真偽之差異圖片或說明，未涉及宣傳醫療效能。

四、完整刊登依本法核准之標籤及說明書，未記載前三款事項或招徠銷售之內容。

五、衛教宣導。

第3條

前條第五款衛教宣導，以有下列各款情形之一者為限：

一、以健康促進或預防疾病為目的，未涉及特定醫療器材之宣傳。

二、提供醫事人員作為對病人或特定對象之衛教使用，其內容僅刊登疾病介紹、術後照顧、特定醫療器材裝置介紹、回診訊息或注意事項，未包括醫療器材業者聯絡資訊。

第4條

第二條第五款衛教宣導有下列情形之一者，視為醫療器材廣告：

一、與醫療器材平面廣告，刊登於同一版面或具連續性質之版面。

二、併同醫療器材動態廣告，連續刊播。

三、衛教宣導之演出或代言者，與其他醫療器材廣告之演出或代言者相同，而使消費者誤認為廣告或有誤認之虞。

第5條

本法第八條第六款所稱混入或附著影響品質之異物，指於醫療器材完整包裝內，混入或附著足以影響品質之物質。

第6條

本法第十條第一款用詞，定義如下：

一、製造：指以物理或化學方法，將材料、物質或零組件轉變成醫療器材，不以完成包裝、貼標或滅菌為必要之作業。

二、包裝：指附加於醫療器材本體外，用以維持醫療器材之價值、狀態，包

22

[Enforcement Rules of the Medical Devices Act] (Promulgated 2021.04.26)

Article 1

These Rules are enacted in accordance with Article 84 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

Any of the following circumstances shall not be deemed as medical device advertisements as stipulated in Article 6 of the Act:

1. Publications that only include the name of the medical device, price, special price discounts, specifications, material, product appearance images, name, address, or telephone number of the manufacturer, without any promotion of medical efficacy.

2. Statements regarding special events which do not involve the promotion of medical efficacy.

3. Images or explanations distinguishing between genuine and counterfeit medical devices, without any promotion of medical efficacy.

4. Complete publications of labels and instructions as approved in accordance with the Act, without including the matters in the preceding three subparagraphs or content soliciting sales.

5. Health education promotion.

Article 3

Health education promotion as referred to in Subparagraph 5 of the preceding Article shall be limited to any of the following circumstances:

1. Aimed at health promotion or disease prevention, and not involving promotion of specific medical devices.

2. Provided to medical personnel for health education use for patients or specific individuals, with content only including disease introduction, postoperative care, introduction to specific medical device installation, follow-up visit information or precautions, and without including contact information of medical device enterprises.

Article 4

If any of the following circumstances apply to health education promotion as referred to in Subparagraph 5 of Article 2, it shall be regarded as medical device advertisement:

1. Presented on the same page or consecutive pages as printed advertisements for medical devices.

2. Continuously broadcast together with dynamic advertisements for medical devices.

3. If the performer or endorser of the health education promotion is the same as that in other medical device advertisements, causing or likely to cause consumers to misconstrue it as an advertisement.

Article 5

The term "foreign substance mixed or attached that affects quality" as stated in Subparagraph 6, Article 8 of the Act, refers to substances mixed or attached within the complete packaging of a medical device that are sufficient to affect its quality.

Article 6

The terminology used in Subparagraph 1, Article 10 of the Act is defined as follows:

Translated by RegDesk AI

1. Manufacture: Refers to the process of converting materials, substances, or components into medical devices by physical or chemical means; completion of packaging, labeling, or sterilization is not a necessary operation.

2. Packaging: Refers to materials added to the exterior of the medical device itself to maintain the value or condition of the medical device, including but not limited to ...

Translated by RegDesk AI

括分裝之作業。

三、貼標：指於該醫療器材最小販售包裝或本體上，附貼標籤之作業。

四、最終驗放：指最終確認醫療器材產品，與其設計開發預定之安全、效能及品質合致，並予放行之作業。

第7條

本法第十一條所稱維修，指將醫療器材故障、損壞或劣化部分，予以修護，或以拆解方式進行醫療器材檢查之作業。但有下列情形之一者，不包括在內：

一、產品髒污之清潔。

二、依原廠手冊，對產品進行功能測試、點檢相關配件、更換耗材或其他自主之保養。

三、瑕疵品整機之更換。

四、產品之校正。

第8條

依本法第十三條第二項規定申請醫療器材商核准登記，其登記事項如下：

一、醫療器材商種類。

二、醫療器材商名稱。

三、醫療器材商營業地址及醫療器材販賣業者倉庫地址。

四、負責人姓名及國民身分證統一編號，或身分證明文件號碼。

五、營業項目。

六、屬本法第十五條所定製造業者或從事輸入、維修之販賣業者，其醫療器材技術人員姓名及國民身分證統一編號，或身分證明文件號碼。

七、開（停）業狀態。

八、醫療器材屬中央主管機關依本法第十八條公告之種類、品項，並限制販售或供應之型態者，其公告規定應登記事項。

九、其他經中央主管機關公告之事項。

第9條

依本法第十三條第二項規定申請醫療器材商許可執照者，應填具申請書，並檢附下列文件、資料，及繳納執照費，向直轄市、縣（市）主管機關提出：

一、應聘僱技術人員者，其聘僱關係及所聘僱人員之證明文件。

二、醫療器材商為公司者，其公司登記、公司組織章程影本；商業者，其商業登記證明文件影本。

三、公司或商業以外之機構、學校、法人或團體，其目的事業主管機關依本

23

Sub-packaging Operation.

3. Labeling: Refers to the operation of affixing labels on the smallest sales packaging or the body of the medical device.

4. Final Release: Refers to the operation for final confirmation that the medical device product meets the intended safety, performance, and quality as designed and developed, and is to be released.

Article 7

The term "maintenance" as referred to in Article 11 of this Act means the operation that repairs the failed, damaged, or deteriorated parts of a medical device, or inspects the medical device by disassembly. However, the following situations are not included:

1. Cleaning of product contaminants.

2. Conducting functional tests, inspecting related accessories, replacing consumables, or other autonomous maintenance on the product according to the original manufacturer's manual.

3. Replacement of the entire defective unit.

4. Calibration of the product.

Article 8

When applying for approval and registration of a medical device business pursuant to Paragraph 2, Article 13 of this Act, the registration items are as follows:

1. Type of medical device business.

2. Name of the medical device business.

3. Business address of the medical device business and warehouse address of the medical device vendor.

4. Name and National Identification Number, or identification document number, of the responsible person.

5. Business items.

6. For manufacturers as defined in Article 15 of this Act or vendors engaged in importation or maintenance, the name and National Identification Number, or identification document number, of their medical device technical personnel.

7. Business status (start/stop).

8. For medical devices that fall under types or items announced by the central competent authority pursuant to Article 18 of this Act, and forms of restricted sale or supply, the registration items required by announcement.

9. Other matters announced by the central competent authority.

Article 9

When applying for a permit license for a medical device business in accordance with Paragraph 2, Article 13 of this Act, the applicant shall fill out an application form, attach the following documents and materials, and pay the license fee to the municipal or county (city) competent authority:

1. For required technical personnel, proof of employment relationship and related personnel certification documents.

Translated by RegDesk AI

2. If the medical device business is a company, a copy of the company registration and articles of incorporation; if a commercial entity, a copy of the business registration certificate.

3. For institutions, schools, juristic persons, or groups other than companies or businesses, their purposes and business approval documents by the□□□□ (competent authority) according to this Act.

Translated by RegDesk AI

法第十三條第四項出具之同意函。

四、醫療器材販賣業者，其營業地址、場所、儲存醫療器材之倉庫及主要設備之平面略圖。

五、從事本法第十條第一款製造之醫療器材製造業者，其工廠登記證明文件影本。但依工廠管理輔導法規定免辦理工廠登記者，免附。

六、其他經直轄市、縣（市）主管機關指定之文件、資料。

前項第二款公司或商業為新設立者，應由直轄市、縣（市）主管機關先發給籌設許可文件；於檢附該籌設許可文件辦理公司登記、商業登記或工廠登記及取得證明文件後，報該主管機關發給醫療器材商許可執照。

第10條

直轄市、縣（市）主管機關核發醫療器材商許可執照時，應於許可執照，載明本法第九條至第十一條所定醫療器材商種類及營業項目。

第11條

醫療器材商許可執照，應懸掛於營業處所之明顯位置。

第12條

本法施行前，醫療器材商已依藥事法第二十七條第一項規定申請核准登記，取得藥商許可執照者，於本法施行後，免重新申請醫療器材商許可執照；原核准登記事項有變更者，應依本法第十三條第二項規定辦理變更登記，並重新核發醫療器材商許可執照。

第13條

醫療器材商依本法第十三條第二項規定，辦理第八條登記事項變更者，應自事實發生之日起三十日內為之。

第14條

前條登記事項變更，應向原核准登記之主管機關辦理變更登記。

前項變更，其涉及地址以外之公司或商業登記事項者，應先向商業主管機關辦理變更登記。

第15條

依本法第十五條第一項規定聘僱技術人員之輸入醫療器材販賣業者，包括醫療器材許可證所有人或登錄者，及其授權輸入者。

第16條

醫療器材商因遷移至原發給醫療器材商許可執照以外之直轄市、縣（市）

24

Consent letter issued in accordance with Article 13, Paragraph 4 of the Act.

4. For medical device dealers, a schematic floor plan of the business address, premises, warehouse for storing medical devices, and major equipment.

5. For manufacturers engaged in the manufacture of medical devices as specified in Article 10, Subparagraph 1 of the Act, a copy of the factory registration certificate. However, those exempt from factory registration in accordance with the Factory Management and Counseling Act are exempt from attachment.

6. Other documents and information as designated by the competent authority of the municipality or county (city).

If a company or business under Subparagraph 2 of the preceding paragraph is newly established, the competent authority of the municipality or county (city) shall first issue a preparatory establishment permit; after attaching the preparatory permit to process company registration, business registration, or factory registration and obtaining the certificate, an application shall be submitted to the competent authority to issue a medical device business permit license.

Article 10

When issuing a medical device business permit license, the competent authority of the municipality or county (city) shall specify on the license the types of medical device business and business activities defined in Articles 9 to 11 of the Act.

Article 11

The medical device business permit license shall be prominently displayed at the place of business.

Article 12

Prior to the implementation of this Act, medical device businesses that have applied for and obtained a pharmaceutical business permit license in accordance with Article 27, Paragraph 1 of the Pharmaceutical Affairs Act shall not be required to reapply for a medical device business permit license upon the enforcement of this Act; if there is any change to the items originally approved and registered, the business shall process a change of registration according to Article 13, Paragraph 2 of the Act, and a new medical device business permit license shall be reissued.

Article 13

A medical device business that makes changes to the registration details as specified in Article 8, according to Article 13, Paragraph 2 of the Act, shall do so within 30 days from the date the fact occurs.

Article 14

Changes to the registration details in the preceding article shall be handled by applying for registration of change with the original competent authority that approved and registered the business.

If the change involves company or business registration details other than the address, the change in registration must first be completed with the commercial authority.

Article 15

Dealers importing medical devices who employ technical personnel in accordance with Article 15, Paragraph 1 of the Act include the holders or registrants of the medical device license and their authorized importers.

Article 16

Translated by RegDesk AI

When a medical device business relocates to a municipality or county (city) other than the one that originally issued the medical device business permit license,

Translated by RegDesk AI

營業者，應向原核准登記之主管機關辦理歇業；其所領醫療器材許可證，得免繳銷。

第17條

依本法第三十一條規定公開或提供之資料，包括醫療器材商依醫療器材許可證核發與登錄及年度申報準則規定，辦理查驗登記或登錄時所檢附之資料。

前項資料公開之方式如下：

一、刊載於政府公報或其他政府出版品。

二、利用政府電信網路傳送或於政府網站公開。

三、其他足以使公眾得知之方式。

第18條

本法第三十二條所稱最小販售包裝，指直接販售予消費者或醫事機構之包裝。

第19條

醫療器材商依本法第三十三條規定，就醫療器材標籤、說明書或包裝所為之刊載，其方式及內容，應符合下列規定：

一、國內製造之醫療器材，其標示應以正體中文為主，所附外文文字應小於中文。但經核准製造專供外銷者，不在此限。

二、最小販售包裝，應以正體中文載明品名、許可證字號或登錄字號及許可證所有人或登錄者之名稱、地址，並依能辨明之方式，刊載製造日期及有效期間，或保存期限。

第20條

醫療器材商依本法第三十四條第四項規定通報時，其通報內容應包括下列事項：

一、醫療器材商名稱。

二、通報人聯繫方式。

三、醫療器材名稱。

四、許可證字號或登錄字號。

五、產品型號。

六、知悉無法繼續製造、輸入或不足供應該醫療器材之虞之日期。

七、不足供應之原因。

八、庫存量。

九、預估可供應時間。

十、其他經中央主管機關指定之資訊。

25

Operators shall apply for business cessation with the original competent authority that approved their registration; the medical device licenses they hold may be exempt from cancellation.

Article 17

The information disclosed or provided in accordance with Article 31 of this Act includes the information submitted by medical device firms for inspection registration or listing in accordance with the Medical Device License Issuance and Registration and Annual Report Standards.

The methods of public disclosure of the aforementioned information are as follows:

1. Publication in government gazettes or other government publications.

2. Transmission via government telecommunications networks or disclosure on government websites.

3. Other methods sufficient to make the information known to the public.

Article 18

The term "smallest sales packaging" as referred to in Article 32 of this Act means the packaging that is sold directly to consumers or medical institutions.

Article 19

When medical device firms make representations on medical device labels, instructions for use, or packaging in accordance with Article 33 of this Act, the methods and contents shall comply with the following regulations:

1. For domestically manufactured medical devices, labeling shall primarily be in Traditional Chinese, and any attached foreign language text shall be smaller than the Chinese text. However, those approved for manufacture exclusively for export are not subject to this restriction.

2. The smallest sales packaging shall be clearly labeled in Traditional Chinese with the product name, license number or registration number, and the name and address of the license holder or registrant. The manufacturing date and expiration date, or shelf life, shall be indicated in a discernible manner.

Article 20

When medical device firms report under Paragraph 4, Article 34 of this Act, the report shall include the following information:

1. Name of the medical device firm.

2. Contact information of the reporting person.

3. Name of the medical device.

4. License number or registration number.

5. Product model number.

6. Date when it was known that manufacturing, importation, or sufficient supply of the medical device could not be continued.

7. Reason for insufficient supply.

8. Inventory quantity.

9. Estimated time of supply availability.

10. Other information as designated by the central competent authority.

Translated by RegDesk AI

第21條

醫療器材許可證所有人或登錄者，依本法第四十一條第一項規定申請刊播醫療器材廣告者，其應檢具之文件、資料如下：

一、醫療器材廣告申請核定表。

二、說明書、標籤核定本影本；屬第一等級醫療器材者，以其市售說明書、標籤或包裝影本，及表明其內容真實無偽意旨之切結書代之。

三、宣傳內容包括與醫療效能無關之產品特性者，其佐證資料。

四、其他經中央主管機關指定之文件、資料。

第22條

依本法第四十一條核准刊播之醫療器材廣告，其內容應包括下列事項：

一、許可證或登錄之產品名稱。

二、許可證所有人或登錄者之名稱。

三、醫療器材許可證或登錄字號。

四、醫療器材廣告核准刊播文件字號。

醫療器材廣告內容涉及醫療器材效能、使用方法、注意事項、標籤、說明書、包裝或廠商地址資訊者，應以該產品查驗登記或登錄之內容為限。

第23條

依本法第四十一條申請刊播之醫療器材廣告，其內容有下列情形之一者，不予核准：

一、內容不實、誇張或易生誤解。

二、未以公正、客觀及相同基準之方式，與他人產品進行效能或性能比較。

三、違反法規規定。

第24條

依本法第四十三條規定，申請醫療器材廣告核准文件有效期間展延者，應填具醫療器材廣告展延申請書及查檢表，向原核准機關提出。

第25條

醫療器材許可證所有人或登錄者依本法第四十九條第一項規定通報者，應於發現有危害人體健康之虞之次日起七日內，以中央主管機關指定之電子系統為之；必要時，得以紙本、電子郵件、傳真或電話方式為之。

前項通報之內容如下：

一、醫療器材許可證所有人或登錄者之名稱及聯繫方式。

二、醫療器材許可證字號或登錄字號、型號、批號或序號、國內已銷售數量及庫存品數量。

26

Article 21

The holder or registrant of a medical device license, when applying for publication or broadcast of medical device advertisements in accordance with Article 41, Paragraph 1 of this Act, shall submit the following documents and information:

1. Medical Device Advertisement Approval Application Form.

2. Copy of the approved instructions for use and label; for Class I medical devices, copies of the commercially available instructions for use, labels, or packaging and a declaration attesting to the authenticity and truthfulness of the content may be used instead.

3. Supporting documentation for promotional content involving product characteristics unrelated to medical efficacy.

4. Other documents and information as specified by the central competent authority.

Article 22

The content of medical device advertisements approved for publication or broadcast in accordance with Article 41 of this Act shall include the following particulars:

1. The product name as stated on the license or registration.

2. Name of the license or registration holder.

3. Medical device license or registration number.

4. Document number of the medical device advertisement publication/broadcast approval.

If the medical device advertisement content involves efficacy, method of use, precautions, labeling, instructions for use, packaging, or address information of the manufacturer, such content shall be limited to that registered or recorded for the product.

Article 23

For medical device advertisements applied for publication or broadcast pursuant to Article 41 of this Act, approval will not be granted in any of the following circumstances:

1. The content is untrue, exaggerated, or likely to cause misunderstanding.

2. Any comparison of efficacy or performance with other products is not conducted using fair, objective, and consistent criteria.

3. Violation of regulatory provisions.

Article 24

Any application for extension of the validity period of a medical device advertisement approval document in accordance with Article 43 of this Act shall be submitted to the original approval authority by filling out the Medical Device Advertisement Extension Application Form and Checklist.

Article 25

When the holder or registrant of a medical device license makes a notification according to Article 49, Paragraph 1 of this Act, such notification shall be submitted via the electronic system specified by the central competent authority within seven days from the day following discovery of any potential harm to human health; where necessary, such notification may be made in writing, by email, fax, or telephone.

The content of the aforementioned notification shall include the following:

1. Name and contact information of the medical device license holder or registrant.

Translated by RegDesk AI

2. Medical device license number or registration number, model, batch or serial number, quantity sold domestically, and inventory quantity.

Translated by RegDesk AI

三、有危害人體健康或有危害之虞之事實及理由。

四、採取矯正預防措施之內容，及預定完成之期日。

五、其他經中央主管機關指定之資訊。

依前二項通報時，尚未採取矯正預防措施者，前項第四款通報內容，應於合理期間或中央主管機關指定期限內補正。

醫療器材許可證所有人或登錄者完成矯正預防措施後，應製作矯正預防措施成果報告留存備查；其內容包括下列事項：

一、危害或危害之虞存否之確認；確有危害或危害之虞者，其原因事實。

二、所採行之矯正預防措施內容，及實施期程與成果。

三、警訊內容揭露之期日、方式及對象。

第26條

檢舉人檢舉違反本法規定之案件時，得以書面、言詞、電子郵件或其他方式敘明下列事項，向主管機關提出：

一、檢舉人姓名、國民身分證統一編號或身分證明文件號碼、聯絡方式及地址。

二、被檢舉人姓名與地址，或公司、商業名稱、負責人姓名及營業地址。

三、涉嫌違規之具體事項、違規地點、相關資料或可供調查之線索。

前項第二款、第三款事項，檢舉人無法查明者，得免敘明。

以言詞檢舉者，應由受理檢舉機關製作紀錄，並與檢舉人確認其檢舉內容。

受理檢舉機關對檢舉事項無管轄權者，應於確認管轄機關後七日內移送該有管轄權之機關，並通知檢舉人。

第27條

主管機關接獲前條檢舉後，應迅速確實處理，並自接獲檢舉之次日起三十日內，將處理情形通知檢舉人。

第28條

本法第五十九條所定檢舉不良醫療器材，或未取得許可證或登錄而製造、輸入之醫療器材經查獲者，直轄市、縣（市）主管機關，應依其查獲情形，以下列基準計點，核發獎金予檢舉人：

一、未取得許可證或登錄而製造、輸入醫療器材：四點至十點。

二、以批發方式轉售未取得許可證或登錄而製造、輸入之醫療器材：二點至五點。

三、轉讓、零售、運送、寄藏、媒介或意圖販賣而陳列未取得許可證或登錄

27

3. Facts and reasons indicating harm or potential harm to human health.

4. The content of corrective and preventive measures adopted, and the scheduled date of completion.

5. Other information as designated by the central competent authority.

If at the time of the notification under the preceding two paragraphs, corrective and preventive measures have not yet been adopted, the content under subparagraph 4 of the preceding paragraph shall be supplemented within a reasonable period or within a time limit specified by the central competent authority.

After the holder or registrant of the medical device license has completed the corrective and preventive measures, a corrective and preventive measure effectiveness report shall be prepared and retained for future reference; the contents thereof shall include the following:

1. Confirmation as to whether harm or the risk of harm exists; if harm or the risk of harm in fact exists, the facts and reasons therefor.

2. Details of the corrective and preventive measures implemented, their implementation schedule, and results.

3. The date, manner, and recipients of the safety alert disclosure.

Article 26

When an informant reports a case in violation of the provisions of this Act, they may state the following items in writing, orally, by email, or by other means to the competent authority:

1. The informant’s name, National ID number or other identity document number, contact information, and address.

2. The name and address of the reported party, or the company/business name, responsible person’s name, and business address.

3. Concrete facts concerning the alleged violation, location of the violation, relevant materials, or clues that may assist the investigation.

If the informant is unable to ascertain the items in subparagraphs 2 and 3 of the preceding paragraph, these may be omitted.

Oral reports shall be recorded by the receiving authority, and the contents of the report shall be confirmed with the informant.

If the receiving authority does not have jurisdiction over the reported matter, it shall, within seven days after confirming the competent authority, transfer the case to the authority with jurisdiction and notify the informant.

Article 27

After receiving a report referred to in the preceding article, the competent authority shall handle the matter promptly and properly and shall notify the informant of the handling status within thirty days from the day following receipt of the report.

Article 28

For reporting defective medical devices as stipulated in Article 59 of this Act, or for medical devices manufactured or imported without obtaining a license or registration and are found through investigation, the municipal or county (city) competent authority shall, based on the findings of the investigation and following the point system below, issue a reward to the informant:

Translated by RegDesk AI

ENGLISH TRANSLATION · Orig. Pg 30 (cont.)

Item	Points
1. Manufacturing or importing medical devices without obtaining a license or registration	4 to 10 points
2. Reselling by wholesale medical devices manufactured or imported without a license or registration	2 to 5 points
3. Transfer, retail, transportation, storage, brokerage, or displaying with the intent to sell medical devices without obtaining a license or registration	

Translated by RegDesk AI

而製造、輸入之醫療器材：二點至三點。

四、製造、輸入或販賣不良醫療器材：二點至三點。

前項每點獎金之數額，由直轄市、縣（市）主管機關視情況訂定，並編列預算支應。

第29條

依前條規定發給檢舉人之獎金，被檢舉人獲無罪判決或裁罰處分經廢止、撤銷，非因檢舉不實所致者，主管機關得不請求檢舉人返還。

第30條

檢舉案件有下列情形之一者，不予獎勵：

一、匿名。

二、檢舉人姓名、身分文件或檢舉內容虛偽不實。

三、無具體內容。

四、主管機關或其他機關於接獲檢舉前，已發覺違反本法規定之案件。

第31條

二人以上聯名檢舉第二十八條之案件，其獎金應由全體檢舉人具領。二人以上分別檢舉案件而有相同部分者，其獎金應發給最先檢舉者；無法分別先後者，平均發給之。

第32條

主管機關對於檢舉人之姓名、年齡、地址、文書、圖畫、消息、相貌、身分資料或其他足資辨別檢舉人之物品，除法律另有規定外，應予保密；有洩密者，應依個人資料保護法、刑法或其他法律處罰或懲處。

對於檢舉人之檢舉書、筆錄或其他資料，應以密件保存，並禁止第三人閱覽或抄錄。

第33條

受理檢舉之主管機關對於檢舉人之安全，於必要時，得洽請警察機關提供保護。

前項檢舉人因檢舉案件而受有威脅、恐嚇或其他危害安全之行為或有發生之虞者，主管機關應洽請警察機關依法處理。

第34條

本細則自中華民國一百十年五月一日施行。

28

As for the manufacture or import of medical devices: 2 to 3 points.

4. Manufacture, import, or sale of substandard medical devices: 2 to 3 points.

The amount of each reward point in the preceding paragraph shall be determined by the competent authorities of the municipality, county (city) according to circumstances, and shall be provided for in the budget.

Article 29

If the reward granted to the informant in accordance with the preceding article is followed by an acquittal of the reported party or the penalty decision is annulled or revoked, and not due to a false report, the competent authority may choose not to request the informant to return the reward.

Article 30

No reward shall be granted in any of the following circumstances:

1. Anonymous reports.

2. Where the informant's name, identity documents, or the content of the report are false or untrue.

3. Lack of specific content.

4. The competent authority or other agencies have already discovered the case violating the provisions of this Act before receiving the report.

Article 31

For cases under Article 28 reported jointly by two or more people, the reward shall be jointly claimed by all informants. Where two or more people report the same case separately and the content overlaps, the reward shall be given to the person who reported first; if it is not possible to distinguish the order, the reward shall be divided equally.

Article 32

Unless otherwise provided by law, the competent authority shall keep confidential the name, age, address, documents, drawings, information, appearance, identity information or any item sufficient to identify the informant; anyone who leaks such information shall be punished or disciplined in accordance with the Personal Data Protection Act, the Criminal Code, or other laws.

The informant's report, transcripts, or other related materials shall be kept as confidential documents, and third parties shall be prohibited from viewing or copying them.

Article 33

If necessary, the competent authority that receives the report may request the police agencies to provide protection for the safety of the informant.

If the informant is threatened, intimidated, or otherwise endangered, or it is likely that such situations might occur due to the report, the competent authority shall request the police agencies to handle the matter according to law.

Article 34

These Implementation Rules shall come into force on May 1, 2021 of the Republic of China (Year 110).

Translated by RegDesk AI

【醫療器材分類分級管理辦法】(112.08.22修正)

第1條

本辦法依醫療器材管理法第三條第二項規定訂定之。

第2條

醫療器材就其功能、用途、使用方法及工作原理，視其應用科別，分類如下：

一、臨床化學及臨床毒理學。

二、血液學、病理學及基因學。

三、免疫學及微生物學。

四、麻醉科學。

五、心臟血管醫學科學。

六、牙科學。

七、耳鼻喉科學。

八、胃腸病科學及泌尿科學。

九、一般、整形外科手術及皮膚科學。

十、一般醫院及個人使用裝置。

十一、神經科學。

十二、婦產科學。

十三、眼科學。

十四、骨科學。

十五、物理醫學科學。

十六、放射學科學。。

第3條

醫療器材，依其風險程度，分級如下：

一、第一等級：低風險性。

二、第二等級：中風險性。

三、第三等級：高風險性。

第4條

醫療器材分類分級之品項，規定如附表。

醫療器材除前項附表規定者外，其功能、用途或工作原理特殊者，得依下列原則判定其分級：

一、同一醫療器材符合二以上分類、分級或品項者，以其較高風險性等級定之。

29

[Regulations for Classification and Grading Administration of Medical Devices] (Amended on 2023.08.22)

Article 1

These Regulations are enacted pursuant to Article 3, Paragraph 2 of the Medical Devices Act.

Article 2

Medical devices shall be classified, according to their function, purpose, method of use, and operating principles, into the following categories according to their applications in medical specialties:

1. Clinical Chemistry and Clinical Toxicology.

2. Hematology, Pathology, and Genetics.

3. Immunology and Microbiology.

4. Anesthesiology.

5. Cardiovascular Medicine.

6. Dentistry.

7. Otorhinolaryngology.

8. Gastroenterology and Urology.

9. General and Plastic Surgery and Dermatology.

10. General Hospital and Personal Use Devices.

11. Neurology.

12. Obstetrics and Gynecology.

13. Ophthalmology.

14. Orthopedics.

15. Physical Medicine.

16. Radiology.

Article 3

Medical devices, according to their degree of risk, are graded as follows:

1. Class I: Low risk.

2. Class II: Medium risk.

3. Class III: High risk.

Article 4

The specific items for the classification and grading of medical devices are prescribed in the attached table.

For medical devices not covered by the attached table in the preceding paragraph, if their functions, purposes, or operating principles are special, their classification may be determined according to the following principles:

Translated by RegDesk AI

1. Where a single medical device meets the criteria for two or more categories, grades, or items, it shall be assigned the highest applicable risk grade.

Translated by RegDesk AI

二、醫療器材附（配）件，其原廠產品說明書載明專用於特定醫療器材者，除前項附表另有規定者外，以該特定醫療器材等級定之。

三、二以上醫療器材組成之組合產品，適用於二以上醫療器材分類、分級或品項者，以其較高風險性等級定之。

四、以醫療器材作用為主之含藥醫療器材，除前項附表另有規定者外，以第三等級醫療器材定之。

第5條

醫療器材商或民眾，得向中央主管機關查詢醫療器材分級或其他相關事項。

前項查詢者，應填具查詢單，並檢附下列相關文件、資料，及繳納費用，向中央主管機關提出：

一、原廠產品說明書：包括使用方法、功能及工作原理；其非正體中文或英文版本者，應另附正體中文或英文譯本。

二、分類分級參考資料：美國、歐盟或其他國家對該查詢產品已為分類分級之參考資料；無參考資料者，免附。

除前項文件、資料外，中央主管機關得視需要，要求查詢者提供其他相關文件、資料。。

第6條

醫療器材之功能、用途或工作原理，未符合附表所列品項之鑑別範圍者，其分級以第三等級醫療器材定之。

醫療器材已有類似品於國內取得許可證或登錄者，其分級依類似品風險等級定之，或依前條規定向中央主管機關查詢分級，依中央主管機關回覆之風險等級定之。

第7條

本辦法除附表品項代碼「A.3652」、「C.3372」及「C.3970」之規定，自中華民國一百十一年七月一日施行外，自一百十年五月一日施行。

本辦法中華民國一百十二年八月二十二日修正發布之條文，除附表品項代碼「D.1100」、「J.5780」及「M.5844」之規定，自一百十四年八月二十二日施行，品項代碼「I.4040」之規定，自一百十五年八月二十二日施行外，自發布日施行。

30

2. For medical device accessories (or components), if the original manufacturer's product manual specifies exclusive use with a particular medical device, except as otherwise stipulated in the attached table of the preceding paragraph, the classification shall be determined according to the class of that specific medical device.

3. For combination products comprising two or more medical devices that fall under different categories, classifications, or items applicable to two or more medical devices, the highest risk class among them shall apply.

4. For drug-containing medical devices in which the principal intended action is that of a medical device, except as otherwise stipulated in the attached table of the preceding paragraph, classification as Class III medical devices shall apply.

Article 5

Medical device firms or the public may inquire with the central competent authority regarding the classification or other related matters of medical devices.

Those making such inquiries as stipulated in the preceding paragraph shall fill out an inquiry form, attach the following relevant documents and data, and pay the required fees to the central competent authority:

1. Original manufacturer's product manual: including methods of use, functions, and working principles. If the manual is not in Traditional Chinese or English, a translation in Traditional Chinese or English shall also be attached.

2. Reference materials for classification or class: Reference materials indicating the classification or class of the inquired product as established by the United States, the European Union, or other countries; if no such reference material exists, submission is exempted.

In addition to the documents and data listed above, the central competent authority may, as needed, request the inquirer to provide other relevant documents or data.

Article 6

If the function, intended use, or working principle of a medical device does not fall within the identification scope of the items listed in the attached table, it shall be classified as a Class III medical device.

If similar products of the medical device have already obtained permits or are registered domestically, its classification shall be based on the risk class of the similar products, or, in accordance with the preceding Article, an inquiry about the classification may be made to the central competent authority and the classification shall be based on the risk class as replied by the central competent authority.

Article 7

Except for the provisions regarding the codes “A.3652,” “C.3372,” and “C.3970” in the attached table, which shall take effect on July 1, 2022, these Regulations shall be enforced from May 1, 2021.

The amendments to these Regulations promulgated on August 22, 2023, except for the provisions regarding the codes “D.1100,” “J.5780,” and “M.5844” in the attached table, which will take effect on August 22, 2025, and the provision for code “I.4040,” which will take effect on August 22, 2026, shall take effect from the date of promulgation.

Translated by RegDesk AI

【醫療器材技術人員管理辦法】(110.04.01發布)

第1條

本辦法依醫療器材管理法（以下簡稱本法）第十五條第二項規定訂定之。

第2條

本辦法所定技術人員如下：

一、製造業者：

（一）製造體外診斷醫療器材人員。

（二）製造非體外診斷醫療器材人員。

二、從事輸入或維修之販賣業者：

（一）輸入醫療器材技術人員。

（二）維修體外診斷醫療器材人員。

（三）維修非體外診斷醫療器材人員。

同一業者聘僱前項各款技術人員，應至少一人。

第3條

製造體外診斷醫療器材技術人員，應具備下列資格之一：

一、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校醫學工程、醫學檢驗相關科、系、所或學位學程畢業，領有畢業證書，並在醫療器材製造業者從事製造相關業務一年以上。

二、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校理、工、醫、農相關科、系、所或學位學程畢業，領有畢業證書，並在醫療器材製造業者從事製造相關業務三年以上。

第4條

製造非體外診斷醫療器材技術人員，應具備下列資格之一：

一、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校醫學工程相關科、系、所或學位學程畢業，領有畢業證書，並在醫療器材製造業者從事製造相關業務一年以上。

二、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校理、工、醫、農相關科、系、所或學位學程畢業，領有畢業證書，並在醫療器材製造業者從事製造相關業務三年以上。

製造具放射性之非體外診斷醫療器材者之技術人員，除得聘僱具前項資格之一者外，亦得聘僱公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校醫學放射相關科、系、所或學位學程畢業，領有畢業證書，並於醫療器材製造業者從事製造相關業務一年以上之人員。

31

[Regulations for the Management of Medical Device Technical Personnel] (Promulgated on 2021.04.01)

Article 1

These Regulations are enacted pursuant to Article 15, Paragraph 2 of the Medical Devices Act (hereinafter referred to as “the Act”).

Article 2

The technical personnel governed by these Regulations are as follows:

1. Manufacturers:

(1) Personnel manufacturing in vitro diagnostic medical devices.

(2) Personnel manufacturing non-in vitro diagnostic medical devices.

2. Dealers engaged in importation or maintenance:

(1) Technical personnel importing medical devices.

(2) Personnel maintaining in vitro diagnostic medical devices.

(3) Personnel maintaining non-in vitro diagnostic medical devices.

When employing the various technical personnel as specified in the preceding paragraphs, the same entity shall employ at least one person for each item.

Article 3

Technical personnel manufacturing in vitro diagnostic medical devices shall possess one of the following qualifications:

1. Graduation from a domestic public or private junior college or above, or from a foreign junior college or above recognized in accordance with Ministry of Education regulations for recognition of foreign academic credentials, in a department, division, institute, or degree program related to biomedical engineering or medical laboratory science, holding a graduation certificate, and having engaged in relevant manufacturing duties at a medical device manufacturer for at least one year.

2. Graduation from a domestic public or private junior college or above, or from a foreign junior college or above recognized in accordance with Ministry of Education regulations for recognition of foreign academic credentials, in a department, division, institute, or degree program related to science, engineering, medicine, or agriculture, holding a graduation certificate, and having engaged in relevant manufacturing duties at a medical device manufacturer for at least three years.

Article 4

Technical personnel manufacturing non-in vitro diagnostic medical devices shall possess one of the following qualifications:

1. Graduation from a domestic public or private junior college or above, or from a foreign junior college or above recognized in accordance with Ministry of Education regulations for recognition of foreign academic credentials, in a department, division, institute, or degree program related to biomedical engineering, holding a graduation certificate, and having engaged in relevant manufacturing duties at a medical device manufacturer for at least one year.

Translated by RegDesk AI

2. Graduation from a domestic public or private junior college or above, or from a foreign junior college or above recognized in accordance with Ministry of Education regulations for recognition of foreign academic credentials, in a department, division, institute, or degree program related to science, engineering, medicine, or agriculture, holding a graduation certificate, and having engaged in relevant manufacturing duties at a medical device manufacturer for at least three years.

For those manufacturing non-in vitro diagnostic medical devices that possess radioactivity, in addition to employing personnel with one of the foregoing qualifications, manufacturers may also employ personnel who have graduated from a domestic public or private junior college or above, or from a foreign junior college or above recognized in accordance with Ministry of Education regulations for recognition of foreign academic credentials, in a department, division, institute, or degree program related to medical radiology, holding a graduation certificate, and having engaged in relevant manufacturing duties at a medical device manufacturer for at least one year.

Translated by RegDesk AI

第5條

輸入醫療器材技術人員，應具備下列各款資格：

一、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校畢業，領有畢業證書。

二、於醫療器材製造業或販賣業，從事醫療器材製造或醫療器材查驗登記文件資料準備、程序管理及送件實務相關業務一年以上。

三、最近五年內曾接受至少二十小時以上之教育訓練；其教育訓練包括下列課程：

（一）我國醫療器材相關法令。

（二）醫療器材產品製造品質管理系統。

（三）查驗登記文件資料準備及程序管理。

（四）查驗登記送件實務。

（五）醫療器材產品上市後管理。

第6條

維修體外診斷醫療器材技術人員，應具備下列資格之一：

一、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校醫學工程、醫學檢驗相關科、系、所或學位學程畢業，領有畢業證書，並於醫療器材製造或輸入、維修之販賣業者，從事製造或維修相關業務一年以上。

二、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校理、工、醫、農相關科、系、所或學位學程畢業，領有畢業證書，並於醫療器材製造或輸入、維修之販賣業者，從事製造或維修相關業務三年以上。

三、於醫療器材製造或輸入、維修之販賣業者，從事製造或維修相關業務五年以上。

第7條

維修非體外診斷醫療器材技術人員，應具備下列資格之一：

一、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校醫學工程相關科、系、所或學位學程畢業，領有畢業證書，並於醫療器材製造或輸入、維修之販賣業者，從事製造或維修相關業務一年以上。

二、公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校理、工、醫、農相關科、系、所或學位學程畢業，領有畢業證

32

Article 5

Technical personnel for imported medical devices shall possess the following qualifications:

1. Graduation from a public or private junior college or higher, or from a foreign junior college or higher that meets the Ministry of Education's Regulations for Recognition of Foreign Academic Credentials, holding a graduation certificate.

2. At least one year of experience in the medical device manufacturing or distribution industry, engaging in the preparation of documents for medical device manufacturing or medical device registration and inspection, process management, and practical submission-related work.

3. Completion of at least twenty hours of educational training within the last five years; such training shall include the following courses:

(1) Relevant medical device laws and regulations of our country.

(2) Medical device product manufacturing quality management systems.

(3) Preparation of documents and process management for registration and inspection.

(4) Practical submission operations for registration and inspection.

(5) Post-market management of medical device products.

Article 6

Technical personnel repairing in vitro diagnostic medical devices shall possess one of the following qualifications:

1. Graduation from a public or private junior college or higher or from a foreign junior college or higher that meets the Ministry of Education's Regulations for Recognition of Foreign Academic Credentials, majoring in biomedical engineering, medical laboratory science, or a related department, institute, or degree program, holding a graduation certificate, and with at least one year of experience in manufacturing or repairing related work in a medical device manufacturing, importing, or repair distribution business.

2. Graduation from a public or private junior college or higher or from a foreign junior college or higher that meets the Ministry of Education's Regulations for Recognition of Foreign Academic Credentials, majoring in science, engineering, medicine, or agriculture related department, institute, or degree program, holding a graduation certificate, and with at least three years of experience in manufacturing or repairing related work in a medical device manufacturing, importing, or repair distribution business.

3. At least five years of experience in manufacturing or repairing related work in a medical device manufacturing, importing, or repair distribution business.

Article 7

Technical personnel repairing non-in vitro diagnostic medical devices shall possess one of the following qualifications:

1. Graduation from a public or private junior college or higher or from a foreign junior college or higher that meets the Ministry of Education's Regulations for Recognition of Foreign Academic Credentials, majoring in biomedical engineering related department, institute, or degree program, holding a graduation certificate, and with at least one year of experience in manufacturing or repairing related work in a medical device manufacturing, importing, or repair distribution business.

Translated by RegDesk AI

2. Graduation from a public or private junior college or higher or from a foreign junior college or higher that meets the Ministry of Education's Regulations for Recognition of Foreign Academic Credentials, majoring in science, engineering, medicine, or agriculture related department, institute, or degree program, holding a graduation certificate, and with...

Translated by RegDesk AI

書，並於醫療器材製造或輸入、維修之販賣業者，從事製造或維修相關業務三年以上。

三、於醫療器材製造或輸入、維修之販賣業者，從事製造或維修相關業務五年以上。

維修具放射性之非體外診斷醫療器材者之技術人員，除得聘僱具前項資格之一者外，亦得聘僱公、私立專科以上學校或符合教育部辦理國外學歷採認法規之國外專科以上學校醫學放射相關科、系、所或學位學程畢業，領有畢業證書，並於醫療器材製造或輸入、維修之販賣業者，從事製造或維修相關業務一年以上之人員。

第8條

第三條及第四條技術人員，其業務如下：

一、專任駐廠監督醫療器材製造流程。

二、管理醫療器材品質系統文件。

三、管理醫療器材不良事件。

四、管理醫療器材安全監督事項。

五、督導、管理依本法第二十九條所定準則規定事項，並協助提供技術說明或文件資料。

第9條

第五條技術人員，其業務如下：

一、管理依本法第二十九條所定準則規定事項。

二、管理醫療器材不良事件。

三、管理醫療器材安全監督事項。

四、管理醫療器材產品來源及流向文件。

第10條

第六條及第七條技術人員，其業務如下：

一、維修並確認維修後產品之安全及效能。

二、製作並簽署維修紀錄。

維修之販賣業者應保存前項紀錄至少五年。

第11條

技術人員自製造業或販賣業者依本法第十三條第二項辦理登記之日起，每年應接受八小時繼續教育訓練；屆期未完成訓練者，應限期令其改善，屆期未改善者，直轄市、縣（市）主管機關應通知製造業或販賣業者限期辦理技術人員變更登記；屆期未辦理者，依本法第七十條第一項第一款規定處罰。

33

...and has been engaged in manufacturing or maintenance-related business for more than three years at a medical device manufacturer, importer, or maintenance distributor.

3. Has been engaged in manufacturing or maintenance-related business for more than five years at a medical device manufacturer, importer, or maintenance distributor.

Technical personnel engaged in the maintenance of non-in vitro diagnostic medical devices containing radioactive elements, in addition to employing those qualified under the preceding subparagraphs, may also employ graduates from domestic or foreign junior colleges or higher (with the latter's qualifications recognized in accordance with Ministry of Education regulations), who majored in medical radiology or related departments, divisions, institutes, or degree programs, and who hold a graduation certificate and have engaged in manufacturing or maintenance-related business for more than one year at a medical device manufacturer, importer, or maintenance distributor.

Article 8

Technical personnel under Article 3 and Article 4, shall perform the following duties:

1. Serve as full-time supervisors stationed at the factory to oversee the manufacturing process of medical devices.

2. Manage quality system documents for medical devices.

3. Manage adverse events associated with medical devices.

4. Manage matters related to safety supervision of medical devices.

5. Supervise and manage matters stipulated by the standards prescribed in Article 29 of this Act, and assist in providing technical explanations or documentary information.

Article 9

Technical personnel under Article 5, shall perform the following duties:

1. Manage matters stipulated by the standards prescribed in Article 29 of this Act.

2. Manage adverse events associated with medical devices.

3. Manage matters related to safety supervision of medical devices.

4. Manage documents regarding the source and distribution of medical device products.

Article 10

Technical personnel under Article 6 and Article 7, shall perform the following duties:

1. Repair and confirm the safety and performance of the products after maintenance.

2. Prepare and sign maintenance records.

The maintenance distributor shall retain the aforementioned records for at least five years.

Article 11

Translated by RegDesk AI

Technical personnel shall, starting from the date of registration by the manufacturer or distributor in accordance with Article 13, Paragraph 2 of this Act, receive eight hours of continuing education training annually; those who fail to complete the training by the deadline shall be required to make improvements within a specified period. If improvements are not made within the deadline, the competent municipality or county (city) authority shall notify the manufacturer or distributor to change the technical personnel registration within a specified period; failure to do so shall be punished in accordance with Article 70, Paragraph 1, Subparagraph 1 of this Act.

Translated by RegDesk AI

前項繼續教育訓練，包括下列課程：

一、醫療器材相關法令。

二、醫療器材品質管理。

三、醫療器材違規案例解析。

第12條

第五條第三款教育訓練及前條第一項繼續教育訓練，其委任所屬機關（構），或委託其他機關（構）或經認證之法人或團體辦理者，依本法第七十九條第三項所定辦法之規定辦理。

第13條

自本辦法施行之日起三年內，具有國內專科以上學校或經教育部承認之國外專科以上學校理、工、醫、農或其他相關科、系、所或學程畢業之資格，而未符合第三條或第四條所定資格者，得擔任製造業技術人員。

自本辦法施行之日起三年內，未符合第五條、第六條或第七條所定資格者，得擔任輸入販賣業或維修販賣業技術人員。

本辦法施行滿三年之次日起，應符合本辦法所定資格，始得繼續擔任前二項技術人員。

第14條

本辦法自中華民國一百十年五月一日施行。

34

The continuing education training mentioned in the preceding paragraph includes the following courses:

1. Laws and regulations related to medical devices.

2. Quality management of medical devices.

3. Analysis of cases involving violations related to medical devices.

Article 12

The educational training specified in Subparagraph 3, Article 5, and the continuing education training in Paragraph 1 of the preceding article, when entrusted by the competent authority to a subordinate agency (institution), or commissioned to other agencies (institutions) or certified legal persons or organizations for implementation, shall be conducted in accordance with the regulations specified in Paragraph 3, Article 79 of this Act.

Article 13

Within three years from the effective date of these Regulations, those who have graduated from a domestic junior college or above, or a foreign junior college or above recognized by the Ministry of Education, in departments, divisions, institutes, or academic programs related to science, engineering, medicine, agriculture, or other relevant fields, but do not meet the qualifications specified in Article 3 or Article 4, may serve as technical personnel in manufacturing.

Within three years from the effective date of these Regulations, those who do not meet the qualifications specified in Article 5, Article 6, or Article 7 may serve as technical personnel in the import and distribution industry or maintenance and distribution industry.

Starting from the day following the full three years after the implementation of these Regulations, one must meet the qualifications specified herein to continue serving as technical personnel as described in the preceding two paragraphs.

Article 14

These Regulations shall come into force on May 1, 2021.

Translated by RegDesk AI

【醫療器材來源流向資料建立及管理辦法】(110.04.20發布)

第1條

本辦法依醫療器材管理法（以下簡稱本法）第十九條第三項規定訂定之。

第2條

取得醫療器材許可證或完成登錄之醫療器材商，應以電子或書面方式，依本法第十九條第一項規定，建立及保存醫療器材下列供應來源及流向之資料：

一、供應來源資料：

（一）產品識別資訊。

（二）批號或序號。

（三）數量。

（四）輸入者之報關日期。

（五）製造日期及有效期間，或保存期限。

（六）其他中央主管機關指定之項目。

二、流向資料：

（一）供應對象之名稱、地址及聯絡資訊。

（二）產品識別資訊。

（三）批號或序號。

（四）數量。

（五）交貨日期。

（六）製造日期及有效期間，或保存期限。

（七）其他中央主管機關指定之項目。

第3條

非持有醫療器材許可證或完成登錄之醫療器材販賣業者，應以電子或書面方式，依本法第十九條第一項規定，建立及保存醫療器材下列供應來源及流向之資料：

一、供應來源資料：

（一）供應者之名稱、地址及聯絡資訊。

（二）產品識別資訊。

（三）批號或序號。

（四）數量。

（五）收貨日期。

（六）製造日期及有效期間，或保存期限。

（七）其他中央主管機關指定之項目。

35

Regulations on the Establishment and Management of Medical Device Supply Source and Distribution Flow Data (Promulgated on 2021.04.20)

Article 1

These Regulations are enacted pursuant to Paragraph 3 of Article 19 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

Medical device businesses that have obtained medical device licenses or have completed registration shall, in accordance with the provisions of Paragraph 1 of Article 19 of the Act, establish and retain the following data on the sources of supply and distribution flow of medical devices, either electronically or in writing:

1. Supply source data:

(1) Product identification information.

(2) Batch number or serial number.

(3) Quantity.

(4) Customs clearance date of the importer.

(5) Manufacturing date and validity period, or shelf life.

(6) Other items designated by the central competent authority.

2. Distribution flow data:

(1) Name, address, and contact information of the recipient entity.

(2) Product identification information.

(3) Batch number or serial number.

(4) Quantity.

(5) Delivery date.

(6) Manufacturing date and validity period, or shelf life.

(7) Other items designated by the central competent authority.

Article 3

Medical device dealers who have neither obtained a medical device license nor completed registration shall, in accordance with the provisions of Paragraph 1 of Article 19 of the Act, establish and retain the following data on the sources of supply and distribution flow of medical devices, either electronically or in writing:

1. Supply source data:

(1) Name, address, and contact information of the supplier.

(2) Product identification information.

(3) Batch number or serial number.

(4) Quantity.

(5) Date of receipt.

(6) Manufacturing date and validity period, or shelf life.

Translated by RegDesk AI

(7) Other items designated by the central competent authority.

Translated by RegDesk AI

二、流向資料：

（一）供應對象之名稱、地址及聯絡資訊。

（二）產品識別資訊。

（三）批號或序號。

（四）數量。

（五）交貨日期。

（六）製造日期及有效期間，或保存期限。

（七）其他中央主管機關指定之項目。

第4條

醫事機構就其使用之醫療器材，應以電子或書面方式，依本法第十九條第一項規定，建立及保存醫療器材下列供應來源資料：

一、產品識別資訊。

二、批號或序號。

三、數量。

四、供應者或其他提供者之名稱、地址及聯絡資訊。

五、收貨日期。

六、其他中央主管機關指定之項目。

前項醫療器材，屬本法第十九條第二項規定應申報之品項者，除前項資料外，醫事機構應依各別批號或序號，建立及保存接受治療之病人姓名、國民身分證統一編號或身分證明文件號碼及聯絡資料之流向資料。

第5條

依前三條建立及保存之資料，屬本法第十九條第二項公告之品項者，醫療器材商及醫事機構應於每年一月、四月、七月及十月之二十日前，以電子方式申報至中央主管機關建立之系統。但醫事機構之流向資料，不包括在內。

第6條

第二條第一款第一目、第二款第二目、第三條第一款第二目、第二款第二目及第四條第一款所定產品識別資訊，應包括下列項目：

一、品名。

二、許可證字號或登錄字號。

三、型號或規格。

四、其他中央主管機關指定之項目。

第7條

醫療器材商已依本法第三十三條第一項第十款公告，於醫療器材刊載單一

36

II. Distribution data:

(1) Name, address, and contact information of the recipient.

(2) Product identification information.

(3) Batch number or serial number.

(4) Quantity.

(5) Delivery date.

(6) Manufacturing date and period of validity, or expiry date.

(7) Other items designated by the central competent authority.

Article 4

Medical institutions shall, for the medical devices they use, establish and maintain the following supplier source data in electronic or written form in accordance with Article 19, Paragraph 1 of this Act:

1. Product identification information.

2. Batch number or serial number.

3. Quantity.

4. Name, address, and contact information of the supplier or other provider.

5. Date of receipt.

6. Other items designated by the central competent authority.

For the medical devices in the preceding paragraph that are announced under Article 19, Paragraph 2 of this Act as reporting items, in addition to the aforementioned data, medical institutions shall, based on each batch number or serial number, establish and maintain distribution data of the treated patient's name, National Identification Card number or identification document number, and contact information.

Article 5

For data established and maintained in accordance with the preceding three articles that are announced as reporting items under Article 19, Paragraph 2 of this Act, medical device traders and medical institutions shall report electronically to the system established by the central competent authority before the twentieth day of January, April, July, and October each year. However, the distribution data of medical institutions is excluded.

Article 6

The product identification information specified in Article 2, Subparagraph 1, Item 1; Subparagraph 2, Item 2; Article 3, Subparagraph 1, Item 2; Subparagraph 2, Item 2; and Article 4, Subparagraph 1 shall include the following items:

1. Product name.

2. License number or registration number.

3. Model or specification.

4. Other items designated by the central competent authority.

Article 7

Translated by RegDesk AI

If a medical device trader, in accordance with Article 33, Paragraph 1, Subparagraph 10 of this Act, has published the Unique...

Translated by RegDesk AI

識別碼者，醫療器材商及醫事機構依第五條規定申報前條第一款至第三款之產品識別資訊，應以單一識別碼替代。

第8條

醫療器材商及醫事機構依本辦法規定建立資訊之保存期間，除本法第十九條第二項申報品項應永久保存外，其餘為三年。

第9條

本辦法自中華民國一百十年五月一日施行。

37

For identifiers, when medical device firms and medical institutions declare the product identification information specified in Items 1 to 3 of the preceding article in accordance with Article 5, they shall use a single identifier as a substitute.

Article 8

The retention period for information established by medical device firms and medical institutions in accordance with these Regulations, except for the permanent preservation requirement for items declared under Paragraph 2, Article 19 of this Act, shall be three years for all others.

Article 9

These Regulations shall take effect on May 1, 2021.

Translated by RegDesk AI

【醫療器材製造業者設置標準】(109.12.10發布)

第1條

本標準依醫療器材管理法（以下簡稱本法）第二十條第二項規定訂定之。

第2條

本法第十條第一款醫療器材製造業者，其設施、設備及作業區域，應符合下列規定：

一、室內天花板、牆壁及地面，保持平滑無裂痕或縫隙，且易於清潔而不發生粉塵，必要時應採用易於消毒清洗之材料。

二、作業區域有良好之照明及通風設備；必要時，並具有適當之溫度、濕度及潔淨度調節設備。

三、易燃性或危險性原物料、溶劑、中間產品及產品之作業區域，設置適當之防護、急救及隔離設施。

四、設置原料、物料、中間產品及最終產品之倉庫。

五、場所內備供製造人員使用之更衣室、洗手設備，並視需要設置工作衣、帽、口罩、手套及鞋履之洗滌或消毒滅菌設備。

第3條

醫療器材製造業者之場所環境，應保持清潔，並設有完善之排水系統；涉及製造生物技術產品者，應對病原體進行安全防護措施，不得妨礙公共衛生及安全。

第4條

本法第十條第一款醫療器材製造業者，其建築應堅固安全，具有防鼠、防蟲及防塵設計；場所內之排水溝應加蓋。

第5條

場所內作業區域應明確劃分，兼製其他產品時，應避免影響醫療器材之品質及安全；必要時，其作業區域應個別設置或加以有效區隔。

第6條

醫療器材之品質及安全有受環境或空氣潔淨度影響之虞者，作業區域應有環境控制措施；必要時，應設置潔淨室。

前項潔淨室之設置及維護，應符合中央主管機關公告之空調系統作業指引或國際標準組織無塵室標準（ISO14644：Cleanrooms and associated controlled environments）。

38

[Standards for the Establishment of Medical Device Manufacturers] (Promulgated on December 10, 2020)

Article 1

These Standards are established in accordance with Article 20, Paragraph 2 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

The facility, equipment, and operating areas for medical device manufacturers referred to in Article 10, Subparagraph 1 of the Act shall comply with the following requirements:

1. The indoor ceilings, walls, and floors shall be kept smooth, free of cracks or crevices, and easy to clean without generating dust; where necessary, materials that are easily disinfected and cleaned shall be used.

2. The operating area shall be equipped with adequate lighting and ventilation; where necessary, proper facilities for controlling temperature, humidity, and cleanliness shall be provided.

3. Operating areas for flammable or hazardous raw materials, solvents, intermediates, and products shall be equipped with appropriate protective, first-aid, and isolation facilities.

4. Warehouses shall be established for raw materials, materials, intermediates, and final products.

5. Changing rooms and hand-washing facilities for manufacturing personnel shall be provided within the premises, and where necessary, equipment for washing or disinfecting/sterilizing work clothing, hats, masks, gloves, and footwear shall be installed.

Article 3

The premises of medical device manufacturers shall be kept clean and equipped with a comprehensive drainage system. For those involved in the manufacturing of biotechnology products, biosafety protective measures against pathogens shall be implemented; public health and safety shall not be compromised.

Article 4

The buildings of medical device manufacturers as referred to in Article 10, Subparagraph 1 of the Act shall be sturdy and safe, and be designed to be rodent-proof, insect-proof, and dust-proof. Drains inside the premises must be covered.

Article 5

Operating areas within the premises shall be clearly delineated. Where other products are also manufactured, it should be ensured that the quality and safety of medical devices are not affected. If necessary, the operating areas should be separately established or effectively segregated.

Article 6

Where the quality and safety of medical devices may be affected by the environment or air cleanliness, environmental control measures must be implemented in the operating areas; where necessary, cleanrooms shall be established.

The establishment and maintenance of the cleanrooms referred to in the preceding paragraph shall comply with the operating guidelines for air conditioning systems announced by the central competent authority, or International Organization for Standardization cleanroom standards (ISO 14644: Cleanrooms and associated controlled environments).

Translated by RegDesk AI

第7條

本法第十條第一款醫療器材製造業者，從事滅菌作業時，應設置下列設備：

一、滅菌設備。

二、無菌試驗設備。

前項未執行無菌試驗者，得免設置無菌試驗設備。

第8條

本法第十條第一款醫療器材製造業者，執行包裝或貼標之作業區域，應視作業需要，設置下列設備：

一、度量衡器。

二、分裝設備。

三、包裝設備。

四、封蓋設備。

五、標籤印製設備。

六、批號印製設備。

第9條

醫療器材製造業者，應就其用以證明產品符合規定要求之設施、設備，予以管制、校正、查證、確認及維護，並作成紀錄。

前項紀錄，應依醫療器材品質管理系統準則之規定保存。

第10條

本標準自本法施行之日施行。

39

Article 7

Medical device manufacturers specified in Article 10, Subparagraph 1 of this Act, engaging in sterilization operations, shall install the following equipment:

1. Sterilization equipment.

2. Sterility testing equipment.

Those who do not perform sterility testing as referred to in the preceding paragraph may be exempted from installing sterility testing equipment.

Article 8

Medical device manufacturers specified in Article 10, Subparagraph 1 of this Act, in operation areas where packaging or labeling is conducted, shall, as required by operational needs, install the following equipment:

1. Weighing and measuring equipment.

2. Dispensing equipment.

3. Packaging equipment.

4. Sealing equipment.

5. Label printing equipment.

6. Batch number printing equipment.

Article 9

Medical device manufacturers shall control, calibrate, verify, validate, and maintain the facilities and equipment used as evidence that their products meet regulatory requirements, and shall keep records thereof.

The records referred to in the preceding paragraph shall be preserved in accordance with the provisions of the Medical Device Quality Management System Guidelines.

Article 10

These Standards shall be enforced from the date of implementation of this Act.

Translated by RegDesk AI

【醫療器材品質管理系統準則】(110.04.14.發布)

第一章　總則

第1條

本準則依醫療器材管理法（以下簡稱本法）第二十二條第四項規定訂定之。

第2條

本準則有關醫療器材製造業者之場所設施、設備、組織與人事、生產、品質管制、儲存、運銷、客戶申訴及其他事項之規範，參照國際標準組織醫療器材品質管理系統（ISO13485：Medical devices-Quality management systems-Requirements for regulatory purposes）之內容訂定。

第3條

本準則用詞，定義如下：

一、建議性通告：指於醫療器材交貨後，由製造業者就醫療器材之使用、修正、回收、銷毀或其他有關事項，發布之補充或建議措施之資訊。

二、客戶申訴：指客戶以書面、電訊或口頭方式，對上市醫療器材之特性、品質、耐用性、可靠性、可用性、安全性、功能性或影響其性能之相關服務為不滿之表示。

三、植入式醫療器材：指以器材本體全部或部分依下列方式使用，持續留置於人體三十日以上，並得藉由外科或其他醫療方式取出之器材：

（一）經手術或其他方式植入人體。

（二）直接置放於人體自然腔道內。

（三）直接置放並替代上表皮或眼表面者。

四、上市後監督：指製造業者對已上市之醫療器材，就其實際使用經驗所為系統性之蒐集及分析。

五、產品：指與醫療器材製造有關作業過程之服務、軟體、硬體及加工材料。

六、風險管理：指以系統化應用管理政策、程序及實際操作方式，分析、評估及控制風險之工作。

七、無菌屏障系統：指維持醫療器材使用時，處於最小包裝型態，且無菌狀態之系統。

40

「Medical Device Quality Management System Guidelines」 (Promulgated on 2021.04.14)

Chapter 1 General Provisions

Article 1

These Guidelines are formulated in accordance with Paragraph 4, Article 22 of the Medical Device Act (hereinafter referred to as “the Act”).

Article 2

These Guidelines prescribe the standards related to the premises, facilities, equipment, organization and personnel, production, quality control, storage, distribution, customer complaints, and other matters of medical device manufacturers, with reference to the contents of the International Organization for Standardization’s medical device quality management system (ISO 13485: Medical devices—Quality management systems—Requirements for regulatory purposes).

Article 3

The terms used in these Guidelines are defined as follows:

1. Advisory Notice: Refers to information issued by the manufacturer after delivery of medical devices, providing supplementary or recommended measures regarding the use, modification, recall, destruction, or other relevant matters of the medical device.

2. Customer Complaint: Refers to a written, telephonic, or verbal expression of dissatisfaction by a customer regarding the characteristics, quality, durability, reliability, availability, safety, functionality, or service affecting the performance of a marketed medical device.

3. Implantable Medical Device: Refers to a device which, in whole or in part, is intended to be placed in the human body for more than thirty days, and may be removed by surgical or other medical means, by any of the following means:

(1) Surgically or otherwise implanted into the human body.

(2) Directly placed within a natural body orifice.

(3) Directly placed to replace the skin or ocular surface.

4. Post-Market Surveillance: Refers to the systematic collection and analysis by the manufacturer regarding the actual use experience of medical devices that have been placed on the market.

5. Product: Refers to services, software, hardware, and processed materials related to the processes involved in medical device manufacturing.

6. Risk Management: Refers to the systematic application of management policies, procedures, and practical methods to analyze, assess, and control risks.

7. Sterile Barrier System: Refers to a system that maintains the medical device in a state of minimum packaging and sterility during use.

Translated by RegDesk AI

第二章　品質管理系統

第4條

製造業者應以書面建立符合本準則規定之品質管理系統，並維持其有效性。

製造業者應採取下列措施，建立、實施及維持品質管理系統所定之需求、程序、活動或安排：

一、決定並執行品質管理系統所需之流程。

二、依風險評估監控品質管理系統之流程。

三、決定品質管理系統之實施流程順序及相互作用。

第5條

製造業者對品質管理系統之流程，應採取下列措施：

一、建立及維持系統所定之基準及方法。

二、確保建立系統及維持系統運作中，取得應有之資源及資訊。

三、為達成系統預期結果，採取維持其流程有效性之必要行動。

四、系統運作之監管、分析及必要之量測。

五、建立及保存足資證明系統符合本法及本準則規定之紀錄。

第6條

前條流程之訂定及變更，應經實施品質管理系統及醫療器材之影響評估，並符合本法及本準則規定，始得為之。

第7條

製造業者之產品委託其他業者（以下稱受託者）製造、加工或提供服務時，應就品質管理系統流程足以影響產品之符合性者，簽訂委託書面契約，實施監測。

製造業者應採行措施，確保受託者之製造、加工或提供服務流程，符合委託書面契約、本準則及其他相關法規之規定。

第8條

製造業者應以書面訂定品質管理系統中電腦軟體確效之標準程序，並於初次使用前，予以檢核；電腦軟體內容及應用有變更時，亦同。

前項電腦軟體確效所採用之特定方法及活動，應與該軟體之使用風險相稱，並予記錄。

第9條

品質管理系統應建立文件；其文件之內容，應包括下列事項：

41

Chapter 2 Quality Management System

Article 4

Manufacturers shall establish a written quality management system in accordance with the provisions of these Regulations and maintain its effectiveness.

Manufacturers shall take the following measures to establish, implement, and maintain the requirements, procedures, activities, or arrangements defined in the quality management system:

1. Determine and implement the processes required for the quality management system.

2. Monitor the processes of the quality management system based on risk assessment.

3. Determine the sequence and interaction of the processes implemented in the quality management system.

Article 5

In regard to the processes of the quality management system, manufacturers shall take the following measures:

1. Establish and maintain the criteria and methods as defined by the system.

2. Ensure that appropriate resources and information are obtained during the establishment and operation of the system.

3. Take necessary actions to maintain the effectiveness of processes in order to achieve the intended results of the system.

4. Supervision, analysis, and necessary measurement of the system operation.

5. Establish and retain records sufficient to demonstrate compliance of the system with the provisions of this Act and these Regulations.

Article 6

The establishment and changes of the processes in the preceding Article shall undergo impact assessment on the implementation of the quality management system and medical devices, and may only proceed if they comply with the provisions of this Act and these Regulations.

Article 7

When a manufacturer outsources the manufacturing, processing, or provision of services to other parties (hereinafter referred to as the contractor), a written contract shall be signed and monitoring implemented regarding processes in the quality management system that may affect product conformity.

Manufacturers shall take measures to ensure that the contractor's processes of manufacturing, processing, or service provision comply with the written contract, these Regulations, and other relevant laws and regulations.

Article 8

Manufacturers shall establish in writing standard procedures for computer software validation within the quality management system, and conduct verification prior to initial use; the same shall apply when the content or application of the computer software is changed.

The specific methods and activities adopted for software validation in the preceding paragraph shall be commensurate with the use risk of the software and shall be recorded.

Article 9

Translated by RegDesk AI

The quality management system shall establish documentation; the content of such documentation shall include the following items:

Translated by RegDesk AI

一、品質政策及品質目標之聲明。

二、品質手冊。

三、本準則所定之程序及紀錄。

四、品質管理系統流程之規劃、運作及管制製作之文件及紀錄。

五、其他中央主管機關規定之事項。

第10條

前條第二款品質手冊，其內容應包括下列事項：

一、系統之文件架構。

二、系統之範圍；其內容有排除適用或不實施之情形者，並應載明其理由。

三、系統所定之程序。

四、系統流程間之相互作用。

第11條

製造業者應就每一類型或系列之醫療器材，建立醫療器材檔案，證明其製造符合本法及本準則之規定。

前項醫療器材檔案，應包括下列事項：

一、醫療器材概述、預期用途或目的及標示。

二、產品規格。

三、製造、包裝、儲存、搬運及運銷之規格、程序。

四、量測及監管程序。

五、必要之安裝要求。

六、必要之服務要求。

前項事項，得以文件或提供索引之方式呈現。

第12條

製造業者對於品質管理系統之文件，應予管制。

前項管制程序，應以書面建立；其內容包括下列事項：

一、文件發布及下達前之審查及核定；其修正，亦同。

二、版次及變更歷程與狀態之辨識確認。

三、各別場所應適用文件之備置情形。

四、版次文件及內容易讀性之確認。

五、必要外部原始文件有效性之確認，及該文件分發之管制。

六、文件毀損或滅失之預防。

七、失效文件之辨識確認及誤用預防措施。

前項第一款修正，原核定或其他指定部門，應參考相關背景資料為之。

42

1. Statement of quality policy and quality objectives.

2. Quality manual.

3. The procedures and records stipulated by these Regulations.

4. Documents and records prepared for the planning, operation, and control of the quality management system processes.

5. Other matters stipulated by the central competent authority.

Article 10

The quality manual referred to in Item 2 of the preceding article shall include the following items:

1. Document structure of the system.

2. Scope of the system; if any content is excluded or not implemented, the reasons shall be stated.

3. Procedures established by the system.

4. Interaction among system processes.

Article 11

The manufacturer shall establish a medical device file for each type or series of medical device to demonstrate that its manufacture complies with the provisions of the Act and these Regulations.

The medical device file in the preceding paragraph shall include the following items:

1. Overview of the medical device, its intended use or purpose, and labeling.

2. Product specifications.

3. Specifications and procedures for manufacturing, packaging, storage, handling, and distribution.

4. Measurement and monitoring procedures.

5. Necessary installation requirements.

6. Necessary servicing requirements.

The foregoing items may be presented in documents or by providing an index.

Article 12

The manufacturer shall control the documentation of the quality management system.

The control procedures referred to in the preceding paragraph shall be established in writing and shall include the following items:

1. Review and approval before issuance and release of documents; the same applies to revisions.

2. Identification and confirmation of versions, revision history, and status.

3. Provision of applicable documents at each respective location.

4. Confirmation of versioned documents and readability of content.

5. Confirmation of validity for necessary external original documents and control of their distribution.

6. Prevention of damage or loss of documents.

7. Identification and confirmation of obsolete documents and measures to prevent misuse.

Translated by RegDesk AI

For revisions under Item 1 of the preceding paragraph, the original approval department or other designated department shall refer to relevant background information.

Translated by RegDesk AI

製造業者應明定失效文件之保存期限，確保於醫療器材有效期間內，得取得其製造及測試之資料，並不得少於相關法規規定之期限。

第13條

製造業者應製作符合本準則規定之紀錄，並妥善保存；紀錄應保持清晰易讀、易於鑑別及檢索。

製造業者應以書面建立前項紀錄之管制程序；其管制內容包括鑑別、儲存、保全、檢索、保護、保存期限及處理。

第一項紀錄之保存期限，應不少於醫療器材有效期間，且不得少於產品自製造業者放行之日起三年。但其他法規規定較長者，從其規定。

製造業者應依個人資料保護法之規定，訂定並執行紀錄內機敏健康資訊之保護措施。

第三章　製造業者最高管理階層責任

第14條

製造業者最高管理階層（以下簡稱最高管理階層）應就品質管理系統之建立、實施及有效維持予以確認，並就下列事項提出參與之佐證：

一、客戶需求及法令適用之內部傳達。

二、品質政策之建立。

三、品質目標之建立。

四、管理階層審查。

五、所需資源之供給。

第15條

最高管理階層，應確認前條第一款傳達內容之正確性，並確保其履行。

第16條

最高管理階層，應確保第十四條第二款品質政策符合製造業者之設立宗旨；其內容包括下列事項：

一、承諾遵行品質管理系統要求，並維持該系統有效性。

二、品質目標建立及審查所依循之架構。

品質政策之適用性應經審查，並於製造業者組織內進行溝通，確保人員之瞭解。

第17條

最高管理階層，應確認各部門及階層完成第十四條第三款品質目標之建立。

43

Manufacturers shall specify the retention period of obsolete documents to ensure access to manufacturing and testing data during the valid period of the medical device, and such period shall not be less than the period stipulated by relevant regulations.

Article 13

Manufacturers shall prepare records that comply with the provisions of these Guidelines and properly retain them. The records shall be clear, easily readable, identifiable, and retrievable.

Manufacturers shall establish written procedures for the control of the aforementioned records; the control shall cover identification, storage, protection, retrieval, retention period, and disposition.

The retention period of the records specified in Paragraph 1 shall not be less than the validity period of the medical device, and shall not be less than three years from the date the product is released by the manufacturer. However, if other laws and regulations require a longer period, those requirements shall apply.

Manufacturers shall, in accordance with the provisions of the Personal Data Protection Act, establish and implement protective measures for sensitive health information contained in the records.

Chapter 3 Responsibilities of Top Management of Manufacturers

Article 14

The top management of the manufacturer (hereinafter referred to as "top management") shall confirm the establishment, implementation, and effective maintenance of the quality management system, and provide evidence of involvement in the following matters:

1. Internal communication of customer requirements and regulatory applicability.

2. Establishment of quality policy.

3. Establishment of quality objectives.

4. Management review.

5. Provision of necessary resources.

Article 15

Top management shall confirm the accuracy of the contents communicated under Item 1 of the preceding Article and ensure their implementation.

Article 16

Top management shall ensure that the quality policy specified in Item 2, Article 14 is consistent with the manufacturer's business objectives; the contents shall include:

1. Commitment to comply with the requirements of the quality management system and to maintain its effectiveness.

2. Framework for the establishment and review of quality objectives.

The applicability of the quality policy shall be reviewed and communicated within the manufacturer’s organization to ensure personnel understanding.

Article 17

Top management shall confirm that all departments and levels have established the quality objectives required under Item 3 of Article 14.

Translated by RegDesk AI

前項品質目標，應依品質政策訂定；其內容包括符合法規與產品要求可加以量測，並應完成之事項。

第18條

最高管理階層，應確認下列事項：

一、品質管理系統之規劃，應符合品質目標及第四條至第八條之規定。

二、品質管理系統之變更，應保持系統之完整性。

第19條

最高管理階層，應以書面規定內部人員之責任及職權，並使其知悉。

前項人員中，擔任與品質有關之管理、執行及查證者，最高管理階層應賦予其行使職權之獨立性，並訂定其執行職務間之關係。

第20條

最高管理階層，應指派一人為品質管理系統之管理代表，並就下列權責以書面定之：

一、確認品質管理系統書面流程之建立。

二、向最高管理階層提出品質管理系統有效性確認及必要改進之報告。

三、加強全體人員對相關法令及客戶要求之認知。

第21條

最高管理階層，應於組織內建立適當之溝通流程，確保有關品質管理系統有效性之事項得以反映。

第22條

製造業者應以書面訂定管理階層審查之參與程序；其內容應包括品質政策、目標及品質管理系統變更或改進之評估。

最高管理階層應依前項程序，定期審查品質管理系統，確保其合適性、適當性及有效性，並製作紀錄及保存。

第23條

前條審查，應包括下列事項：

一、對產品或服務之意見或評論。

二、客戶申訴之處理。

三、對中央主管機關之報告。

四、內部或外部稽核之結果。

五、流程之監管、量測及其結果。

六、產品之監管、量測及其結果。

44

The quality objectives in the preceding paragraph shall be established in accordance with the quality policy; their content shall include compliance with regulations and measurable product requirements, as well as the matters to be accomplished.

Article 18

Top management shall ensure the following matters:

1. The planning of the quality management system shall comply with the quality objectives and the provisions of Articles 4 to 8.

2. Changes to the quality management system shall maintain the integrity of the system.

Article 19

Top management shall specify in writing the responsibilities and authorities of internal personnel and ensure their awareness thereof.

For those personnel engaged in management, execution, or verification related to quality, top management shall grant independence in exercising their authority, and stipulate the relationships among the execution of their duties.

Article 20

Top management shall appoint a management representative for the quality management system and specify in writing the following rights and responsibilities:

1. Confirm the establishment of documented procedures for the quality management system.

2. Report to top management on verification of the effectiveness of the quality management system and necessary improvements.

3. Enhance the overall awareness of relevant laws and customer requirements among all personnel.

Article 21

Top management shall establish appropriate communication processes within the organization to ensure that matters concerning the effectiveness of the quality management system are reflected.

Article 22

Manufacturers shall establish in writing procedures for participation in management reviews; the content shall include evaluation of the quality policy, objectives, and changes or improvements to the quality management system.

Top management shall periodically review the quality management system in accordance with the preceding procedures to ensure its suitability, adequacy, and effectiveness, and shall create and retain records.

Article 23

The review in the preceding article shall include the following:

1. Feedback or comments on products or services.

2. Handling of customer complaints.

3. Reports to the central competent authority.

4. Results of internal or external audits.

5. Monitoring, measurement, and results of processes.

Translated by RegDesk AI

6. Monitoring, measurement, and results of products.

Translated by RegDesk AI

七、矯正措施。

八、預防措施。

九、前次審查結論之後續處置。

十、可能影響品質管理系統之變更。

十一、改進作為之建議。

十二、配合法令增修之因應措施。

第24條

第二十二條之紀錄，其內容應包括下列事項：

一、審查之事項及其內容。

二、為維持品質管理系統及其流程合適性、適當性與有效性，必要之改進措施。

三、因應客戶要求有關產品之改進措施。

四、配合法令增修之因應措施。

五、執行第二款至前款措施之資源需求。

第四章　資源管理

第25條

製造業者應確認並提供第十四條第五款所需之資源，以維持品質管理系統有效實施，並符合法令及客戶之要求。

第26條

從事影響產品品質工作之人員，應具備必要之技能或經驗，或接受適當之教育及訓練，確保得勝任其工作。

第27條

製造業者應以書面，就其人員之能力培育、必要訓練及職責正確認知，訂定下列事項：

一、從事影響產品品質工作人員能力之認定。

二、維持人員能力必要訓練或其他措施之提供。

三、前款訓練或措施有效性之評估。

四、人員認知作業活動對品質目標達成之相關性及重要性之確保。

五、人員教育、訓練、技能及經驗之錄音、錄影、相片、證書或證明紀錄之保存。

第28條

製造業者應以書面訂定基礎設施之條件，以符合產品要求，並避免產品混

45

7. Corrective actions.

8. Preventive actions.

9. Follow-up actions on the conclusions of the previous review.

10. Changes that may affect the quality management system.

11. Recommendations for improvement actions.

12. Response measures for cooperating with amendments of laws and regulations.

Article 24

The records specified in Article 22 shall include the following items:

1. The matters reviewed and their content.

2. Necessary improvement actions to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes.

3. Improvement actions regarding products in response to customer requirements.

4. Response measures for cooperating with amendments of laws and regulations.

5. Resource requirements for implementing the actions specified in Item 2 to the preceding item.

Chapter 4 Resource Management

Article 25

The manufacturer shall identify and provide the resources required pursuant to Article 14, Item 5, in order to maintain the effective implementation of the quality management system and to comply with legal and customer requirements.

Article 26

Personnel engaged in work affecting product quality shall possess the necessary skills or experience, or receive appropriate education and training, to ensure their competence in their work.

Article 27

The manufacturer shall stipulate in writing the following matters regarding personnel competency development, necessary training, and correct awareness of duties:

1. Identification of the competence of personnel engaged in work affecting product quality.

2. Provision of necessary training or other measures to maintain personnel competence.

3. Evaluation of the effectiveness of the training or measures specified in the preceding item.

4. Ensuring personnel are aware of the relevance and importance of their activities to the achievement of quality objectives.

5. Preservation of records such as audio, video, photographs, certificates, or documentation of personnel education, training, skills, and experience.

Article 28

The manufacturer shall stipulate in writing the conditions of the infrastructure in order to meet product requirements and to prevent product mixing.

Translated by RegDesk AI

淆及其處理失序。

前項設施，應包括下列事項：

一、建築物、工作空間及相關設施。

二、硬體及軟體之製程設備。

三、運輸、通訊、資訊系統或其他支援服務。

前項設施維護足以影響產品品質者，製造業者應訂定其維護內容及實施頻率，並製作紀錄及保存。

工作環境管制、監控及量測所用設備之維護，準用前項規定。

第29條

為確保產品製造之品質，製造業者應以書面訂定工作環境之規範，並應予以監控及管制。

前項規範，應包括下列事項：

一、人員與產品或作業環境接觸，足以影響醫療器材安全或性能者，其人員健康、清潔及服裝條件。

二、確保於特殊環境條件下工作之臨時人員，其應具備之能力或受具備該等能力之人監管。

第30條

為防止其他產品、工作環境或人員造成污染，製造業者應以書面訂定受污染或易受污染產品之管制措施。

製造業者應以書面訂定無菌醫療器材之微生物或微粒污染管制要求；其組裝或包裝流程，並應維持必要之清潔度。

第五章　產品實現

第31條

製造業者應以書面訂定產品實現之風險管理流程。

製造業者應依前項管理流程，規劃及建立產品實現所需之程序，並應符合品質管理系統之其他程序要求。

前項規劃內容，應配合製造業者運作方式以書面定之，並依其情形，包括下列事項：

一、品質目標及產品要求。

二、必要流程及文件之建立，個別產品所應提供含基礎設施、工作環境之特定資源。

三、個別產品之查證、確效、監控、量測、檢查、試驗、搬運、儲存、運銷與來源追溯措施，及其允收基準。

and their management disorder.

The aforementioned facilities shall include the following items:

1. Buildings, workspaces, and related facilities.

2. Hardware and software process equipment.

3. Transportation, communication, information systems, or other support services.

For facilities maintenance in the preceding paragraph, if it is sufficient to affect product quality, the manufacturer shall specify the maintenance content and implementation frequency, and produce and retain records.

The maintenance of equipment used for work environment control, monitoring, and measurement shall be implemented mutatis mutandis in accordance with the preceding paragraph.

Article 29

To ensure the quality of product manufacturing, the manufacturer shall establish written specifications for the work environment and monitor and control it.

The aforementioned specifications shall include the following items:

1. Where personnel contact with the product or the working environment is sufficient to affect the safety or performance of the medical device, conditions on personnel health, cleanliness, and clothing.

2. For temporary personnel working under special environmental conditions, the required competencies or supervision by personnel with such competencies.

Article 30

To prevent contamination caused by other products, the work environment, or personnel, the manufacturer shall establish in writing control measures for contaminated or easily contaminated products.

The manufacturer shall also establish in writing the control requirements for microbiological or particulate contamination for sterile medical devices; during assembly or packaging processes, the necessary level of cleanliness shall be maintained.

Chapter V Product Realization

Article 31

The manufacturer shall establish in writing a risk management process for product realization.

The manufacturer shall plan and establish the procedures needed for product realization according to the management process in the preceding paragraph, and these procedures shall comply with other requirements of the quality management system.

The content of the aforementioned planning shall be established in writing to align with the operation mode of the manufacturer, and, as applicable, include the following items:

1. Quality objectives and product requirements.

2. Establishment of necessary processes and documents, and the specific resources for each product, including basic infrastructure and work environment.

3. Verification, validation, monitoring, measurement, inspection, testing, handling, storage, distribution, and traceability measures for each product, as well as their acceptance criteria.

Translated by RegDesk AI

四、足資證明產品實現流程及最終產品符合要求之紀錄。

第一項風險管理之實施，應製作紀錄並保存。

第32條

製造業者應確認下列事項：

一、客戶訂單之要求，包括交貨前後。

二、符合現行規定或預期用途之必要要求。

三、產品應適用之法令。

四、使用者接受醫療器材符合預定性能及安全之必要訓練。

五、其他必要事項。

第33條

製造業者於接受產品訂單前，應審查與產品有關之要求，並確認下列事項：

一、訂單所載之產品要求。

二、合約或訂單內容與原協議不同之處理。

三、法令之遵守。

四、使用者訓練之提供。

五、履約能力之具備。

前項審查及確認之措施，應製作紀錄並保存。

客戶非以書面提出對產品之要求者，製造業者應於接單前確認之。

製造業者與客戶間之約定有變更者，應修正相關文件，並確認已告知相關人員。

第34條

製造業者應以書面訂定下列客戶溝通事項：

一、產品資訊。

二、客戶詢問、合約或訂單之處理。

三、申訴及其他客戶回饋。

四、建議性通告。

前項事項，製造業者應依法令規定向主管機關申請、通知或陳報。

第35條

製造業者應以書面訂定產品設計開發之程序及要求，其內容應包括下列事項：

一、設計開發之期程，及各期程所應為之審查、實施之查證、確效與設計移轉措施。

47

4. Records sufficient to demonstrate the product realization process and that the final product meets the requirements.

Records shall be created and maintained for the implementation of risk management referred to in Paragraph 1.

Article 32

The manufacturer shall confirm the following matters:

1. The requirements of customer orders, including before and after delivery.

2. Necessary requirements to comply with current regulations or the intended use.

3. Laws and regulations applicable to the product.

4. The necessary training to ensure that users are able to operate the medical device in accordance with its intended performance and safety.

5. Other necessary matters.

Article 33

Before accepting product orders, manufacturers shall review the requirements related to the product and confirm the following:

1. Product requirements specified in the order.

2. Handling of discrepancies between the contents of contracts or orders and original agreements.

3. Compliance with laws and regulations.

4. Provision of user training.

5. Capability to fulfill the contract.

The review and confirmation measures from the preceding paragraph shall be recorded and maintained.

If customers do not submit product requirements in writing, the manufacturer shall confirm such requirements before accepting the order.

If there are changes to agreements between the manufacturer and the customer, relevant documents shall be revised and confirmation obtained that relevant personnel have been informed.

Article 34

Manufacturers shall specify in writing the following matters related to customer communication:

1. Product information.

2. Handling of customer inquiries, contracts, or orders.

3. Complaints and other customer feedback.

4. Advisory notices.

For the matters in the preceding paragraph, the manufacturer shall apply to, notify, or report to the competent authority in accordance with legal requirements.

Article 35

Manufacturers shall specify in writing the procedures and requirements for product design and development. The content shall include the following:

Translated by RegDesk AI

1. The schedule of design and development, as well as the reviews, verification, validation, and design transfer measures to be carried out at each stage.

Translated by RegDesk AI

二、人員於各期程中之權責。

三、追溯設計開發輸出至其輸入項目之方法。

四、產品實現所需資源，包括人員之必要能力。

前項書面文件，應予保存，並適時更新之。

第36條

製造業者應審查下列設計開發輸入事項之適當性，並予核定、記錄及保存：

一、根據預期用途所定之功能、性能、可用性及安全要求。

二、適用之法令要求及標準。

三、適用之風險管理評估結果及研擬措施之輸出。

四、類似產品設計所提供之資訊。

五、其他有關產品與產品實現流程設計及開發之基本要求。

前項各款事項，應明確、完整及合理，並具可供查證或確效之方式。

第37條

產品設計開發輸出，應包括下列事項：

一、符合前條第一項所核定之內容，並具查證方式。

二、提供採購、生產及服務所需之必要資訊。

三、產品之允收基準。

四、產品安全及正確使用之必要特性。

前項輸出，應經權責人員核准，始得發布；其紀錄，應予保存。

第38條

製造業者應依第三十五條規定之程序及要求，執行設計開發之審查；其審查內容，應包括下列事項：

一、設計開發結果符合要求之評估。

二、各期程所需必要措施之確認及提出。

前項審查之參與者，應包括設計與開發部門之代表、設計開發結果所影響部門之代表，及其他技術人員。

審查結果及所提出之必要措施，應製作紀錄並保存。

前項紀錄內容，應明確記載審查標的、審查人員及審查日期。

第39條

為確保產品設計開發輸出符合輸入之要求，製造業者應以書面明定查證計畫，並據以執行。

前項計畫之內容，應包括查證方法、允收基準，及必要之統計技術與樣本

48

2. Responsibilities and authorities of personnel during each stage.

3. Methods for tracing design and development outputs to their input items.

4. Resources required for product realization, including necessary personnel competencies.

The written documents in the preceding paragraph shall be maintained and updated in a timely manner.

Article 36

Manufacturers shall review the appropriateness of the following design and development input items, approve them, record, and retain them:

1. Functionality, performance, usability, and safety requirements defined according to the intended use.

2. Applicable legal requirements and standards.

3. Applicable risk management assessment results and the outputs of the mitigation measures formulated.

4. Information provided by the design of similar products.

5. Other fundamental requirements related to product and product realization process design and development.

The items in each subparagraph of the preceding paragraph shall be explicit, complete, and reasonable, and shall include means of verification or validation.

Article 37

Product design and development outputs shall include the following items:

1. Conformance to the contents approved in the preceding article, Paragraph 1, with means of verification.

2. Provision of necessary information for procurement, production, and service.

3. Product acceptance criteria.

4. Necessary features for product safety and correct usage.

The outputs in the preceding paragraph shall be approved by personnel with authority before release; the records thereof shall be retained.

Article 38

Manufacturers shall, in accordance with the procedures and requirements specified in Article 35, conduct reviews of design and development; the content of such reviews shall include the following items:

1. Evaluation of whether the design and development results meet requirements.

2. Confirmation and proposal of necessary measures required at each stage.

Participants in the review under the preceding paragraph shall include representatives from the design and development department, representatives from departments affected by the design and development outputs, and other technical personnel.

Records of the review results and proposed necessary measures shall be prepared and retained.

Translated by RegDesk AI

The contents of the records in the preceding paragraph shall clearly specify the subject of the review, the personnel involved, and the date of the review.

Article 39

To ensure that product design and development outputs meet input requirements, manufacturers shall specify a verification plan in writing and implement it accordingly.

The contents of the preceding plan shall include verification methods, acceptance criteria, and necessary statistical techniques and samples.

Translated by RegDesk AI

數決定理由。

依產品之預定用途，使用時有與其他醫療器材連接或有介面者，第一項之查證應包括連接或介接符合輸入之要求。

查證結果、處置及所提出之必要措施，應製作紀錄並保存。

第40條

為確保設計開發之最終產品合於特定應用或預期用途，製造業者應以書面訂定確效計畫；其內容包括確效方法、允收基準，及必要之統計技術與樣本數決定理由。

前項確效對象，應選擇首次產製或其他具代表性之產品；其選擇理由，製作紀錄並保存。

依產品之預定用途，使用時有與其他醫療器材連接或有介面者，第一項之確效，應包括連接或介接符合產品之特定應用或預期用途。

第一項之確效，應於產品放行前完成；其確認結果及提出之必要措施，應製作紀錄並保存。

第41條

製造業者應以書面訂定設計開發結果移轉至實際製造之程序，確保其製程及生產能力已經查證符合要求；其移轉之過程及內容，應製作紀錄並保存。

第42條

製造業者應以書面訂定設計開發變更之管制程序，確定變更對醫療器材功能、性能、可用性、安全性、法規要求及預期用途之影響程度。

前項管制，應就變更內容審查、查證、必要之確效及核准，並於變更前完成。

前項審查，應包括評估變更對產品組成部分、製程中或已交貨產品、風險管理輸入或輸出與產品實現流程之影響。

變更結果、審查及相關之必要措施，應製作紀錄並保存。

第43條

製造業者應建立每一型號或系列之醫療器材設計開發檔案，並保存之。

前項檔案，應包括可證明符合設計開發要求，及設計與開發變更之紀錄；或以索引方式提供。

第44條

製造業者應以書面訂定確認程序，確保所採購之產品符合其要求。

製造業者應訂定供應商之評估及選擇基準；其訂定之考量因素如下：

49

Justification for decision.

According to the intended use of the product, if, during use, it is connected to or interfaces with other medical devices, the verification referred to in Paragraph 1 shall include the requirement that the connection or interface complies with import requirements.

The results of verification, measures taken, and necessary proposed actions shall be documented and retained.

Article 40

To ensure that the final product of design and development meets specific applications or intended uses, the manufacturer shall establish a written validation plan. The contents shall include validation methods, acceptance criteria, and, where necessary, statistical techniques and justification for sample size determination.

For the validation referred to in the preceding paragraph, the manufacturer shall select the initial production or other representative products as validation objects; the rationale for such selection shall be documented and retained.

According to the intended use of the product, if, during use, it is connected to or interfaces with other medical devices, the validation under Paragraph 1 shall include the requirement that the connection or interface complies with the specific application or intended use of the product.

The validation under Paragraph 1 shall be completed before the product is released; the confirmation results and any necessary corrective measures shall be documented and retained.

Article 41

The manufacturer shall establish in writing the procedures for transferring design and development results to actual manufacturing, to ensure that the manufacturing processes and production capabilities have been verified to meet requirements; the transfer process and its contents shall be documented and retained.

Article 42

The manufacturer shall establish in writing procedures for controlling design and development changes, to determine the extent of impact such changes have on medical device function, performance, usability, safety, regulatory requirements, and intended use.

The controls specified in the preceding paragraph shall include review, verification, necessary validation, and approval of the changes, all to be completed prior to implementing said changes.

The review in the preceding paragraph shall include an evaluation of the impact of the changes on product components, products in the production process or already delivered, risk management inputs or outputs, and on the product realization process.

The results of changes, reviews, and relevant necessary measures shall be documented and retained.

Article 43

The manufacturer shall establish and retain a design and development file for each model or series of medical devices.

The file in the preceding paragraph shall include records proving compliance with design and development requirements and records of design and development changes; or may be provided in an indexed format.

Article 44

Translated by RegDesk AI

The manufacturer shall establish in writing the procedures for confirmation, to ensure that procured products conform to requirements.

The manufacturer shall establish criteria for the evaluation and selection of suppliers; the factors considered in establishing these criteria are as follows:

Translated by RegDesk AI

一、供應商提供符合製造業者要求規格產品之能力。

二、供應商過往之實績。

三、供應商所提供產品對醫療器材品質之影響程度。

四、醫療器材之風險。

製造業者應規劃供應商之監控及再評估機制；其管控產品應符合採購要求，並作為再評估之參考。

製造業者發現供應商有未符採購要求者，應採取退貨或其他必要之措施。

前三項之評估、選擇、監控、再評估及必要措施，應製作紀錄並保存。

第45條

前條採購之要求，應包括下列事項，並得逕以書面或其他索引方式查閱：

一、產品規格。

二、有關產品取得之允收、程序、流程及設備。

三、供應商人員之資格。

四、品質管理之系統。

製造業者應於接洽供應商前，確定採購要求之適當性；必要時，製造業者應以書面約定供應商於實施影響採購要求之變更前，先行通知製造業者。

製造業者應依本準則有關追溯性之規定，保存採購資訊之文件、資料及紀錄。

第46條

製造業者應訂定並實施檢查或其他必要查證措施，確保所採購之產品符合採購要求。

前項措施方式及內容之訂定，應參考供應商及所製造醫療器材風險評估之結果。

採購產品有變更者，製造業者應確定該變更對醫療器材產品或其製造過程之影響。

第一項措施，得由製造業者或其客戶於供應商之場所實施者，應於前條採購資訊中，載明其實施之措施及產品放行之方法。

第一項措施之實施，應製作紀錄並保存。

第47條

製造業者應規劃生產及服務流程，並予執行、監控及管制，確保產品符合規格。

前項生產管制之內容，視其情形，包括下列全部或一部事項：

一、生產之書面管制程序及方法。

50

1. The supplier’s ability to provide products that meet the specifications required by the manufacturer.

2. The supplier’s past performance.

3. The extent to which the products provided by the supplier affect the quality of the medical device.

4. The risk associated with the medical device.

The manufacturer shall establish mechanisms for monitoring and re-evaluating suppliers; the products under control shall comply with procurement requirements, and this shall be used as a reference for re-evaluation.

If the manufacturer discovers that a supplier fails to meet procurement requirements, it shall take product return or other necessary actions.

Records shall be made and maintained for the evaluation, selection, monitoring, re-evaluation, and necessary measures in the preceding three items.

Article 45

The procurement requirements of the preceding Article shall include the following matters, and may be directly referenced in writing or by other indexing methods:

1. Product specifications.

2. Acceptance, process, procedures, and equipment related to acquisition of the product.

3. Qualifications of supplier personnel.

4. Quality management systems.

Before contacting suppliers, manufacturers shall confirm the appropriateness of procurement requirements; when necessary, manufacturers shall enter into a written agreement with suppliers requiring prior notification to the manufacturer before implementing changes affecting procurement requirements.

Manufacturers shall keep documents, data, and records related to procurement information in accordance with traceability provisions of these Guidelines.

Article 46

Manufacturers shall establish and implement inspection or other necessary verification measures to ensure that procured products comply with procurement requirements.

The mode and content of the measures in the preceding paragraph shall be determined with reference to the results of risk assessments of suppliers and the manufactured medical device.

When procured products are changed, the manufacturer shall determine the impact of these changes on the medical device or its manufacturing process.

If the measures in Paragraph 1 are to be implemented by the manufacturer or its customer at the supplier’s premises, the measures to be implemented and methods of product release shall be specified in the procurement information in the preceding Article.

Records shall be made and maintained for the implementation of the measures in Paragraph 1.

Article 47

Manufacturers shall plan, execute, monitor, and control production and service processes to ensure that products meet specifications.

Translated by RegDesk AI

Depending on the circumstances, production control content in the preceding paragraph may include all or part of the following items:

1. Written control procedures and methods for production.

Translated by RegDesk AI

二、基礎設施合適性之確認。

三、流程參數及產品特性之監控與量測之實施。

四、實施前款監控與量測之設備完妥性確認。

五、標示及包裝作業之實施。

六、產品放行、交貨及交貨後活動之實施。

製造業者應建立並保存每一批（件）醫療器材之生產管制紀錄；其內容包括本準則所定之追溯範圍及生產與銷售數量，該紀錄應予查證及核定。

第48條

有下列情形之一者，製造業者應以書面訂定該產品清潔或污染管制之措施：

一、產品滅菌或使用前，由製造業者完成清潔。

二、產品以未滅菌狀態供應者，於滅菌或使用前完成清潔。

三、產品無法於滅菌或使用前清潔，而清潔度對使用有重大影響。

四、產品使用時無需滅菌，而其清潔度對使用有重大影響。

五、製程中使用之藥劑，應自產品去除。

前項第一款及第二款情形，於清潔處理前，不適用第二十九條規定。

第49條

製造業者必要時應就特定醫療器材，以書面訂定可供查證之安裝要求事項及允收基準。

製造業者同意客戶之要求，由其本身及其授權代理人以外之第三人安裝醫療器材者，製造業者應提供該第三人符合依前項所定事項及基準之文件。

製造業者應就其本身或其授權代理人所為之安裝，製作紀錄並保存。

第50條

醫療器材之售後有特定規格要求者，製造業者應以書面訂定服務之執行程序，及執行與查證之參考量測方式或其他資料。

前項服務，製造業者或其授權代理人應製作紀錄並保存。

製造業者應分析前項紀錄；其有申訴者，應確認有無處理及處理結果。必要時，應將處理結果納入改善之參考。

第51條

製造業者應保存各滅菌批次之滅菌流程參數紀錄。

前項紀錄之內容，應可追溯至醫療器材之每生產批次。

第52條

51

2. Confirmation of the suitability of infrastructure.

3. Implementation of monitoring and measurement of process parameters and product characteristics.

4. Verification of the readiness of equipment for the monitoring and measurement mentioned in the preceding item.

5. Implementation of labeling and packaging operations.

6. Implementation of product release, delivery, and post-delivery activities.

The manufacturer shall establish and retain production control records for each batch (unit) of medical devices. The contents of such records shall include the traceability scope stipulated in these guidelines and the quantities produced and sold. These records shall be verified and approved.

Article 48

Under any of the following circumstances, the manufacturer shall establish written measures for cleaning or contamination control of the product:

1. The product is cleaned by the manufacturer before sterilization or use.

2. The product is supplied in a non-sterile state and cleaned before sterilization or use.

3. The product cannot be cleaned prior to sterilization or use, and the level of cleanliness has a significant impact on use.

4. The product does not require sterilization during use, but its cleanliness has a significant impact on use.

5. Any agents used in the process must be removed from the product.

In situations described in Subparagraphs 1 and 2 of the preceding paragraph, Article 29 does not apply prior to cleaning.

Article 49

Where necessary, the manufacturer shall establish, in writing, verifiable installation requirements and acceptance criteria for specific medical devices.

Where the manufacturer agrees to a customer’s request for the installation of medical devices by a third party other than the manufacturer itself or its authorized representative, the manufacturer shall provide such third party with documentation that complies with the requirements and criteria set forth in the preceding paragraph.

The manufacturer shall prepare and retain records of installations performed by itself or its authorized representatives.

Article 50

Where specific specifications are required for post-sale medical devices, the manufacturer shall establish, in writing, the execution procedures for such services, as well as the reference measurement methods or other data for implementation and verification.

For the services specified in the preceding paragraph, the manufacturer or its authorized representative shall prepare and retain records.

The manufacturer shall analyze the records specified in the preceding paragraph; if there are complaints, it shall confirm whether they have been handled and the results of such handling. If necessary, the results shall be incorporated as references for improvement.

Translated by RegDesk AI

Article 51

The manufacturer shall retain records of sterilization process parameters for each sterilization batch.

The contents of such records shall be traceable to each production batch of the medical device.

Article 52

Translated by RegDesk AI

醫療器材非經使用或接受服務，無法顯現其生產或服務之缺失者，製造業者應對該生產或服務流程予以確效。

前項確效，應證明生產或服務符合其所預定者；其確效程序，應以書面定之，並包括下列事項：

一、審查基準及核准程序。

二、所需設備規格及實施人員資格。

三、使用之特定方法、程序及允收基準。

四、所採之統計技術方法及樣本數決定之理由。

五、依第十三條規定對紀錄確認之要求。

六、再確效及其基準。

七、確效程序變更之核准。

製造業者應訂定書面程序，於生產或服務提供前，確效其所使用之電腦軟體；其軟體有變更者，亦同。軟體確效及再確效所採方式之擇定，應考量軟體之使用對產品規格符合性之影響程度。

前項確效及再確效結果，及依該結果所得之結論與後續實施之必要行動，應製作紀錄並保存。

第53條

製造業者應以書面訂定滅菌流程及無菌屏障系統確效之程序，其適用範圍包括產品本體；製造流程變更時，亦同。

前項確效結果，及其獲致之結論與後續必要之措施，應製作紀錄並保存。

第54條

製造業者應以書面建立產品實現流程中，識別產品之程序及方式，確保退回產品及其他產品之區隔。

製造業者應於產品實現之生產、儲存、安裝及服務流程，鑑別產品之監測結果符合要求；通過特定檢查、測試或特准之產品，始得放行、使用或安裝。

製造業者應依就本法第十九條第一項所公告一定風險等級之醫療器材，以書面訂定其單一識別系統。

第55條

製造業者應以書面訂定產品追溯程序，規定產品追溯性之範圍與所要求之紀錄。

第56條

前條紀錄涉及植入式醫療器材之追溯者，應包括可能導致不符安全及性能要求之所有零件、材料與生產環境條件。

Article 52

For medical devices whose defects in production or service cannot be manifested unless used or the service has been received, the manufacturer shall validate the corresponding production or service processes.

The validation provided in the preceding paragraph shall demonstrate that the production or service meets its intended requirements; the validation procedures shall be documented in writing and shall include the following matters:

1. Criteria for review and approval procedures.

2. Specifications of necessary equipment and qualifications of the personnel implementing the procedures.

3. Specific methods, procedures, and acceptance criteria used.

4. Statistical techniques adopted and the rationale for determining the sample size.

5. Requirements for record verification in accordance with Article 13.

6. Revalidation and its criteria.

7. Approval of changes to validation procedures.

Manufacturers shall establish written procedures for validation of computer software used prior to production or provision of services; the same shall apply if the software is changed. The selection of validation and revalidation methods for the software shall take into account the degree to which software use affects conformity to product specifications.

The results of validation and revalidation in the preceding paragraph, as well as the conclusions derived therefrom and any necessary subsequent actions implemented, shall be documented and retained.

Article 53

Manufacturers shall establish in writing validation procedures for sterilization processes and sterile barrier systems, which shall apply to the product itself; the same shall apply in case of any change in the manufacturing process.

The results of validation in the preceding paragraph, as well as the conclusions drawn and any subsequent necessary measures, shall be documented and retained.

Article 54

Manufacturers shall establish written procedures and methods for the identification of products during the realization process, to ensure segregation of returned products from other products.

Manufacturers shall, during the processes of production, storage, installation, and service for product realization, identify that the monitoring results of products meet the requirements; only products that have passed specific inspections, tests, or received special approval may be released, used, or installed.

Manufacturers shall, in accordance with the risk class of medical devices announced pursuant to Paragraph 1, Article 19 of this Act, establish in writing their unique device identification system.

Article 55

Manufacturers shall establish written procedures for product traceability, specifying the scope of product traceability and the required records.

Article 56

Translated by RegDesk AI

Records concerning traceability of implantable medical devices as referred to in the preceding article shall include all parts, materials, and manufacturing environmental conditions that may result in nonconformity with safety and performance requirements.

Translated by RegDesk AI

前項植入式醫療器材之製造業者，應要求其產品之物流及經銷者保存物流或銷售紀錄；其以包裹運輸寄送者，有關收貨人之姓名、收貨地址之憑證紀錄，並予保存。

第57條

製造業者應鑑別、確認、維護及保全客戶所提供製造、使用，或構成產品一部分之工具、儲存設備、運輸車輛、開發設計、材料，或其他有形或無形之資產。

前項資產有遺失、損壞或不能使用者，製造業者應通知客戶，並製作紀錄及保存。

第58條

製造業者應以書面訂定防護程序，確保產品之規格不受加工、儲存、搬運及運銷過程之影響。

為避免產品暴露於可預期之狀態或危害，前項過程有改變、污染或損壞醫療器材之虞者，製造業者應實施下列措施：

一、設計及建構合適之包裝與運送容器。

二、前款包裝或容器於特定情況下，無法提供足夠保護者，以書面訂定特別之附加條件；該條件應予管制並製作紀錄。

前二項規定，於產品組成部分之防護，亦適用之。

第59條

製造業者應規劃足資證明產品符合性之監管及量測作業，並備有執行作業必要之相關設備。

前項作業之程序，製造業者應以書面定之。

第一項量測設備之使用，應符合下列規定：

一、初次使用前，以明確之國際或國家標準校正或查證；無明確標準者，記錄所使用之校正或查證基礎。設備啟用後，亦應定期為之。

二、校正或查證後，予以必要之調整，避免導致量測結果不正確。

三、校正狀態予以標示。

四、搬運、維護或儲存時，採避免損壞或變質之措施。

製造業者應依第二項程序，執行校正、查證或調整，並製作紀錄及保存其結果。

第一項設備不符合第三項規定者，製造業者應對其量測結果進行有效性評估，並記錄之；該設備及受影響之產品，應採取適當措施。

製造業者應以書面訂定監管及量測用電腦軟體合適性之確效程序，並於軟

53

The manufacturer of implantable medical devices referred to in the preceding paragraph shall require logistics and distributors handling its products to retain records of logistics or sales; in cases where delivery is made via parcel transport, documentary records of the recipient's name and delivery address shall also be retained.

Article 57

Manufacturers shall identify, verify, maintain, and safeguard tools, storage equipment, transport vehicles, development and design materials, or other tangible or intangible assets provided by customers for manufacturing, use, or as part of the product.

If the assets mentioned in the preceding paragraph are lost, damaged, or rendered unusable, the manufacturer shall notify the customer, produce a record, and retain it.

Article 58

Manufacturers shall establish written protection procedures to ensure that product specifications are not affected during processing, storage, handling, and distribution.

To prevent products from being exposed to foreseeable conditions or hazards, where there is a risk of change, contamination, or damage to medical devices during any of the aforementioned processes, manufacturers shall implement the following measures:

1. Design and construct suitable packaging and shipping containers.

2. Where the packaging or containers described in the preceding subparagraph cannot provide sufficient protection under specific circumstances, special additional conditions shall be stipulated in writing. Such conditions shall be controlled and recorded.

The preceding two paragraphs shall also apply to the protection of product components.

Article 59

Manufacturers shall plan and establish monitoring and measurement operations sufficient to demonstrate product conformity, and shall have at their disposal the necessary related equipment to carry out these operations.

The procedures for the operations in the preceding paragraph shall be established in writing by the manufacturer.

The use of measuring equipment referred to in Paragraph 1 shall meet the following requirements:

1. Before initial use, calibration or verification shall be performed using explicit international or national standards; where no explicit standard exists, the basis for calibration or verification used shall be recorded. Calibration or verification shall also be performed periodically after the equipment is commissioned.

2. Necessary adjustments shall be made after calibration or verification to prevent incorrect measurement results.

3. The calibration status shall be indicated.

4. Measures shall be taken during handling, maintenance, or storage to prevent damage or deterioration.

Manufacturers shall, in accordance with the procedures set out in Paragraph 2, perform calibration, verification, or adjustment, and produce and retain records of the results.

If the equipment in Paragraph 1 does not comply with the provisions in Paragraph 3, the manufacturer shall assess the validity of its measurement results and record them; appropriate measures shall be taken for the equipment and affected products.

Translated by RegDesk AI

ENGLISH TRANSLATION · Orig. Pg 56 (cont.)

Manufacturers shall establish written validation procedures to ensure the suitability of computer software used for monitoring and measurement, and for software...

Translated by RegDesk AI

體使用前，或依實際狀況於使用後或軟體變更時，完成確效。

前項軟體之確效，應依該軟體使用風險，擇定適當方法及活動為之；其結果、獲致之結論及後續之必要行動，應製作紀錄並保存。

前項風險，包括醫療器材達成預期用途能力之影響。

第六章　量測、分析及改進

第60條

製造業者應規劃並執行監管、量測、分析及改進流程，確保產品之符合性，及品質系統之符合與有效性。

前項規劃，應包括統計技術在內之適當方法及其應用範圍之確認。

第61條

為辦理品質管理系統有效性之評估，製造業者應蒐集及監測符合客戶要求之資訊。

製造業者應以書面訂定前項資訊蒐集與使用之方法。

第62條

製造業者應以書面訂定前條資訊接收及處理程序。但法規有特別規定者，從其規定。

前項程序，包括生產及生產後資訊之彙整，作為風險管理之參考，以監管、維持產品符合性及改進流程。

第63條

製造業者應以書面訂定申訴處理程序及辦理期限；其程序內容包括下列事項：

一、申訴之受理與記錄。

二、立案與否之評估。

三、事件之調查。

四、法定通報之事項及方式。

五、依調查結果對產品所為之處置。

六、後續矯正之決定及矯正措施。

前項申訴事項，非因製造業者所致者，製造業者應將申訴內容及調查所得之適當資訊，提供予利害關係人。

第一項紀錄，應包括各款之事項及未依第三款調查之理由，並予保存。

第64條

製造業者應就本法第四十八條第一項之通報、第四十九條之通報、採取矯

54

Validation must be completed before use of the system, or after use or when software changes occur, depending on actual circumstances.

The validation of the aforementioned software shall be conducted by selecting appropriate methods and activities based on the risk associated with the use of the software; the results, conclusions obtained, and necessary subsequent actions shall be documented and retained.

The aforementioned risks include the impact on the ability of the medical device to achieve its intended use.

Chapter 6 Measurement, Analysis, and Improvement

Article 60

Manufacturers shall plan and implement regulatory, measurement, analysis, and improvement processes to ensure product conformity and conformance and effectiveness of the quality system.

The planning in the preceding paragraph shall confirm the inclusion of suitable methods, including statistical techniques, and the scope of their application.

Article 61

For the purpose of assessing the effectiveness of the quality management system, manufacturers shall collect and monitor information that complies with customer requirements.

Manufacturers shall stipulate in writing the methods for collecting and using the information mentioned in the preceding paragraph.

Article 62

Manufacturers shall stipulate in writing the procedures for receiving and handling the information described in the preceding article, unless otherwise provided by regulations, in which case such provisions shall prevail.

The procedures in the preceding paragraph shall include the compilation of information during and after production, to be used as a reference for risk management, regulation, maintenance of product conformity, and improvement processes.

Article 63

Manufacturers shall stipulate in writing the procedures and deadlines for handling complaints; the content of such procedures shall include the following items:

1. Acceptance and recording of complaints.

2. Evaluation of whether to establish a case.

3. Investigation of the incident.

4. Statutory reporting items and methods.

5. Disposal of the product based on the results of the investigation.

6. Decision and implementation of subsequent corrective actions.

If the complaint in the preceding paragraph is not caused by the manufacturer, the manufacturer shall provide the content of the complaint and appropriate information obtained from the investigation to interested parties.

The records in the first paragraph shall include all listed items and reasons for not investigating in accordance with item 3, and such records shall be retained.

Article 64

Translated by RegDesk AI

Manufacturers shall, in accordance with the notification in Article 48, Paragraph 1 of this Act, the notification in Article 49, and the corrective actions taken,

Translated by RegDesk AI

正預防措施及第五十八條第一項之通知、依規定限期回收處理，訂定作業程序。

前項通報、採取矯正措施及回收處理，應製作紀錄並保存。

第65條

製造業者應定期執行內部稽核，確認品質管理系統之有效性及法規符合性。

製造業者應訂定前項稽核之程序，其內容包括與稽核之規劃、執行、記錄及稽核結果報告有關之權責劃分與要求。

第66條

前條稽核規劃之內容，製造業者應考量稽核之對象、項目、內容及地點，並參酌品質管理系統內各流程之重要性及先前稽核之結果訂定之。

前項內容，應包括稽核基準、範圍、頻率、方法及紀錄；稽核人員不得稽核其自身職掌之工作。

第67條

稽核之流程、場所及其結果，應製作紀錄並保存。

受稽核者之管理階層，應就前項稽核結果不符合者，提出矯正措施並及時矯正，去除不符合事項及其原因。

製造業者應就前項矯正措施之執行內容及結果，提出查證報告。

第68條

製造業者應採用適當方法，監管及量測品質管理系統之流程。

經前項方法發現有流程目的未達成者，製造業者應提出矯正措施及實施，確保產品之符合性。

第69條

產品實現流程中，製造業者應依產品特性，以書面訂定於適當階段所為之監管及量測程序，查證產品符合性。

非經前項程序查證者，其產品不得放行。

第一項程序之執行應製作紀錄，其內容包括下列事項：

一、同意放行之權責人員姓名。

二、符合允收基準之證據。

三、使用測試設備者，其設備名稱。

四、植入式醫療器材，其檢查或測試人員姓名。

Article 55

Preventive measures and notifications in accordance with Article 58, Paragraph 1, as well as mandatory recall and treatment within a specified period according to regulations, shall have established operating procedures.

Records shall be made and retained for the notifications, corrective actions, and recall treatments mentioned in the preceding paragraph.

Article 65

Manufacturers shall conduct regular internal audits to verify the effectiveness of the quality management system and regulatory compliance.

Manufacturers shall establish the procedures for the audits mentioned in the preceding paragraph, including delineation of authority and responsibility and requirements related to audit planning, execution, documentation, and reporting of audit results.

Article 66

When planning the audits prescribed in the preceding article, manufacturers shall take into consideration the audit target, item, content, and location, and determine them with reference to the significance of each process within the quality management system and results of previous audits.

The content of the preceding paragraph shall include audit criteria, scope, frequency, methods, and records; auditors shall not audit work for which they are responsible.

Article 67

Records shall be made and retained regarding the audit processes, locations, and results.

The management of the audited parties shall propose and promptly implement corrective actions for nonconformities identified in the audit results mentioned in the preceding paragraph, eliminating nonconformities and their causes.

Manufacturers shall provide a verification report regarding the content and results of the implementation of the corrective actions described in the preceding paragraph.

Article 68

Manufacturers shall adopt appropriate methods to monitor and measure the processes of the quality management system.

If any process is found, through the preceding methods, not to have achieved its intended purpose, the manufacturer shall propose and implement corrective actions to ensure product conformity.

Article 69

In the process of product realization, manufacturers shall, according to product characteristics, establish in writing the monitoring and measuring procedures to be conducted at appropriate stages to verify product conformity.

Products not verified by the procedures described in the preceding paragraph shall not be released.

Records shall be made regarding implementation of the procedures in Paragraph 1, including the following items:

1. Name(s) of the personnel authorized to approve release.

2. Evidence of conformity with acceptance criteria.

3. For those using testing equipment, the name of the equipment.

4. For implantable medical devices, the names of the inspection or testing personnel.

Translated by RegDesk AI

第70條

製造業者應鑑別及管制不符合要求之產品，防止非預期之使用或交貨。

製造業者為符合前項要求，應就不符合原製造業者要求之產品，以書面訂定鑑別、記錄、區隔、評估、廢棄之管制及權責界定程序。

前項評估，應包括調查啟動及通知外部權責機關（構）之決定。

製造業者應將第一項之不符合情況，及後續採行之評估、調查與決策形成理由，製作紀錄並保存。

第71條

製造業者對不合格產品，應視情節，分別或同時採行下列處理方式：

一、去除不符合情況之措施。

二、預防不合格產品作為原預定目的使用或應用之措施。

三、以特殊採用方式為產品之使用、放行或允收。

製造業者採前項第三款處理方式者，應具正當理由，及符合第三十六條第一項第二款規定，並經權責人員核准後，始得為之；核准者之姓名及職稱，並製作紀錄及保存。

第72條

產品交貨後，發現有不符合情況者，製造業者應就其影響或潛在影響採取適當措施，並製作紀錄及保存。

製造業者應以書面訂定對外發布建議性通告之程序，並依該程序規定辦理。

建議性通告之發布，製造業者應製作紀錄並保存。

第73條

製造業者應視產品重加工可能導致之影響，以書面訂定合適之重加工程序，並依原作業指導書之規定審查。

重加工之產品應予查證，確保符合允收基準及法規要求。

重加工之實施，應製作紀錄並保存。

第74條

製造業者應以書面訂定資料蒐集之項目及分析程序，證明品質管理系統之合適性、適當性及有效性。

前項程序，應包括使用統計技術及擇定之實施方法。

第一項分析之資料，應包括監管及量測之結果，其分析應提供下列資訊：

一、客戶對產品、服務或申訴處理過程之意見、評論及表達。

二、產品規格之符合性。

56

Article 70

Manufacturers shall identify and control products that do not meet requirements to prevent unintended use or delivery.

To comply with the previous paragraph, manufacturers shall establish in writing procedures for the identification, recording, segregation, evaluation, disposal, and assignment of authority and responsibility regarding products that do not meet the requirements of the original manufacturer.

The evaluation mentioned in the preceding paragraph shall include decisions on whether to initiate investigations and notify external competent authorities (organizations).

Manufacturers shall document and retain records of the nonconformities referred to in the first paragraph, as well as the subsequent evaluations, investigations, and the reasons for their decisions.

Article 71

Manufacturers, when dealing with nonconforming products, shall, depending on the circumstances, take one or more of the following actions:

1. Measures to eliminate nonconformities.

2. Measures to prevent nonconforming products from being used or applied for their originally intended purpose.

3. Special disposition for the use, release, or acceptance of products.

When a manufacturer takes the third action as mentioned in the preceding paragraph, there must be justified reasons and compliance with the provisions of Article 36, Paragraph 1, Subparagraph 2. Approval must be obtained from authorized personnel before proceeding. The name and position of the approver, as well as related records, shall be documented and retained.

Article 72

After product delivery, if any nonconformities are discovered, the manufacturer shall take appropriate actions based on the impact or potential impact of the nonconformity, and document and retain records of such actions.

Manufacturers shall establish written procedures for issuing advisory notices externally and act in accordance with these procedures.

Records of the issuance of advisory notices shall be documented and retained by the manufacturer.

Article 73

Manufacturers shall, in view of the potential impact of product rework, establish written procedures for appropriate rework and review according to the original operating instructions.

Reworked products shall be verified to ensure they meet acceptance criteria and regulatory requirements.

The implementation of rework shall be documented and records retained.

Article 74

Manufacturers shall, in writing, specify the items for data collection and procedures for analysis to prove the suitability, adequacy, and effectiveness of the quality management system.

The procedures in the preceding paragraph shall include the use of statistical techniques and selected implementation methods.

Translated by RegDesk AI

The data analyzed in the first paragraph shall include results of monitoring and measurement, and the analysis shall provide the following information:

1. Customer opinions, comments, and expressions regarding products, services, or complaint handling processes.

2. Conformity of product specifications.

Translated by RegDesk AI

三、流程與產品之特性與變化趨勢，及適當改進之介入時機。

四、供應商所提供原物料或服務之評估。

五、製造業者接受稽核之結果。

六、必要時，服務報告之評估。

經前項分析發現品質管理系統有不適用、不合宜或無效者，製造業者應依第七十五條至第七十七條規定，將分析結果作為改進之依據。

前項分析結果，應製作紀錄並保存。

第75條

製造業者應依其所定之品質政策及目標為必要之變更，確保並維持品質管理系統之合適性、適當性與有效性，及醫療器材安全與性能。

前項變更，應以稽核結果、上市後監督、資料分析，及矯正與預防措施為依據，並經管理階層審查，確認變更內容後實施。

第76條

製造業者應採取矯正措施，去除不符合事項之發生原因，防止其再發生。

前項矯正措施之實施，不得無故遲延；其措施內容之訂定，應以不符合事項之影響程度為依據。

為實施第一項矯正措施，製造業者應以書面訂定完成下列各款事項之程序：

一、客戶申訴及其他不符合事項之審查。

二、不符合事項原因之判定。

三、矯正措施採行與否之評估。

四、矯正措施之規劃、訂定、實施，及品質系統文件之更新。

五、矯正措施無牴觸法規，及不減損醫療器材安全與性能之查證。

六、矯正措施實施情形及其有效性之審查。

製造業者應就所為不符合事項調查及矯正措施之實施結果，製作紀錄並保存。

第77條

製造業者應採取預防措施，去除潛在不符合事項之可能發生原因。

前項預防措施，其內容之擬訂，應以潛在不符合事項之影響程度為依據。

為實施第一項預防措施，製造業者應以書面訂定完成下列各款事項之程序：

一、潛在不符合事項及其可能發生原因之判定。

二、預防措施採行與否之評估。

3. Characteristics and trends of processes and products, and the appropriate timing for intervention and improvement.

4. Evaluation of raw materials or services provided by suppliers.

5. Results of audits undertaken by the manufacturer.

6. When necessary, evaluation of service reports.

If the analysis in the preceding paragraph identifies any inapplicability, inadequacy, or inefficiency in the quality management system, the manufacturer shall, in accordance with the provisions of Articles 75 to 77, use the analysis results as the basis for improvement.

Records of the analysis results mentioned in the preceding paragraph shall be made and retained.

Article 75

Manufacturers shall make necessary changes in accordance with their established quality policy and objectives to ensure and maintain the suitability, adequacy, and effectiveness of the quality management system, as well as the safety and performance of medical devices.

Such changes as prescribed in the preceding paragraph shall be based on audit results, post-market surveillance, data analysis, and corrective and preventive actions, and shall be reviewed and confirmed by management prior to implementation.

Article 76

Manufacturers shall take corrective actions to eliminate the causes of nonconformities and prevent their recurrence.

The implementation of corrective actions as set forth in the preceding paragraph shall not be unduly delayed; the formulation of such actions shall be based on the degree of impact of the nonconformity.

To implement the corrective actions in Paragraph 1, the manufacturer shall establish, in writing, procedures for completing the following:

1. Review of customer complaints and other nonconformities.

2. Determination of the cause of nonconformity.

3. Evaluation of whether to adopt corrective actions.

4. Planning, formulation, and implementation of corrective actions, and updating of quality system documents.

5. Verification that corrective actions do not violate regulations and do not compromise the safety and performance of medical devices.

6. Review of the implementation and effectiveness of corrective actions.

Manufacturers shall prepare and retain records regarding the investigation of nonconformities and the implementation results of corrective actions.

Article 77

Manufacturers shall take preventive actions to eliminate potential causes of nonconformities.

In formulating the content of the preventive actions described in the preceding paragraph, the degree of impact of potential nonconformities shall be taken as the basis.

To implement the preventive actions in Paragraph 1, the manufacturer shall establish, in writing, procedures for completing the following:

Translated by RegDesk AI

1. Determination of potential nonconformities and their possible causes.

2. Evaluation of whether to adopt preventive actions.

Translated by RegDesk AI

三、預防措施之規劃、訂定、實施，及品質系統文件之更新。

四、預防措施無牴觸法規，及不減損醫療器材安全與性能之查證。

五、預防措施實施情形及其有效性之審查。

製造業者應就所為之潛在不符合事項調查及預防措施之實施結果，製作紀錄並保存。

第七章　附則

第78條

製造業者僅生產附表所列醫療器材品項者，應就其生產之每一類型或系列分別建檔，並實施紀錄管制、申訴處理及矯正與預防措施。

前項業者，除第十一條至第十三條、第四十七條、第五十五條、第六十三條、第六十四條、第六十九條、第七十六條及前條規定外，不適用第二章至前章之規定。

第79條

本準則自中華民國一百十年五月一日施行。

58

3. Planning, formulation, implementation of preventive measures, and updating of quality system documents.

4. Verification that preventive measures do not conflict with regulations and do not diminish the safety and performance of medical devices.

5. Review of the implementation and effectiveness of preventive measures.

Manufacturers shall produce records and retain them regarding the investigation of potential nonconformities and the results of the implementation of preventive measures.

Chapter 7 Supplemental Provisions

Article 78

Manufacturers that only produce the medical device items listed in the attached schedule shall, for each type or series produced, establish separate files and implement record control, complaint handling, corrective and preventive measures.

For the aforementioned manufacturers, except for the provisions of Articles 11 to 13, Article 47, Article 55, Article 63, Article 64, Article 69, Article 76, and the preceding Article, the provisions of Chapter 2 to the preceding chapters do not apply.

Article 79

These Guidelines shall take effect from May 1, 2021 (the 110th year of the Republic of China).

Translated by RegDesk AI

【醫療器材品質管理系統檢查及製造許可核發辦法】(110.02.02發布)

第1條

本辦法依醫療器材管理法（以下簡稱本法）第二十二條第四項規定訂定之。

第2條

醫療器材製造業者，依本法第二十二條第二項規定申請品質管理系統檢查，應填具申請書，檢附附表一所定文件、資料，並繳納費用後，向中央主管機關提出。

前項申請，屬國外製造之輸入醫療器材者，應由代理輸入之醫療器材商，向中央主管機關提出。

第一項文件、資料，有欠缺得補正者，中央主管機關應通知限期補正；屆期未補正者，不予受理。

第一項文件、資料，應以中文或英文記載；非以中文或英文記載者，應另附中文或英文譯本。

第3條

中央主管機關受理前條申請後，應進行醫療器材品質管理系統之檢查，經認定符合醫療器材品質管理系統準則規定者，核發醫療器材製造許可；其未符合者，於書面通知送達之日起二個月內，得提出複評，並以一次為限。

醫療器材製造業者收受前項未符合規定之通知後不服者，或依前項規定申請複評經駁回者，得依法提起訴願。

第4條

除前條之檢查外，中央主管機關並得定期或不定期檢查醫療器材製造業者之品質管理系統。

執行前條或前項檢查時，中央主管機關得通知直轄市、縣（市）主管機關派員參加。

第一項不定期檢查，中央主管機關得不經通知，逕至醫療器材製造業者作業場所為之。

第5條

醫療器材製造許可，應記載下列事項：

一、醫療器材製造業者名稱。

二、醫療器材製造業者地址。

三、許可項目及作業內容。

59

[Regulations for the Inspection of Medical Device Quality Management Systems and Issuance of Manufacturing Permits] (Promulgated on 2021.02.02)

Article 1

These Regulations are enacted in accordance with Article 22, Paragraph 4 of the Medical Devices Act (hereinafter referred to as “the Act”).

Article 2

Medical device manufacturers, when applying for a quality management system inspection in accordance with Article 22, Paragraph 2 of the Act, shall complete an application form, attach the documents and information prescribed in Appendix 1, pay the required fees, and submit the application to the central competent authority.

For applications regarding imported medical devices manufactured abroad, the application shall be submitted to the central competent authority by the medical device dealer acting as the import agent.

Where the documents and information specified in Paragraph 1 are incomplete but can be rectified, the central competent authority shall notify the applicant to make corrections within a specified period; applications not corrected within the prescribed period shall not be accepted.

The documents and information specified in Paragraph 1 shall be provided in Chinese or English; if not originally in Chinese or English, a Chinese or English translation shall be attached.

Article 3

After accepting an application as referred to in the preceding Article, the central competent authority shall conduct an inspection of the medical device quality management system. If the system is deemed to comply with the requirements of the Medical Device Quality Management System Guidelines, a medical device manufacturing permit shall be issued; if found non-compliant, the applicant may submit a request for re-evaluation within two months from the date the written notice is served, with such request limited to one time only.

If a medical device manufacturer disputes the non-compliance notice received as mentioned in the preceding paragraph, or if the request for re-evaluation under the preceding paragraph is rejected, the manufacturer may file an administrative appeal in accordance with the law.

Article 4

In addition to the inspection mentioned in the preceding Article, the central competent authority may also conduct regular or irregular inspections of the quality management system of medical device manufacturers.

When performing inspections referred to in the preceding Article or in the preceding paragraph, the central competent authority may notify the municipal or county (city) competent authority to send personnel to participate.

For irregular inspections referred to in Paragraph 1, the central competent authority may, without prior notice, directly visit the operation site of the medical device manufacturer.

Article 5

The medical device manufacturing permit shall specify the following particulars:

1. Name of the medical device manufacturer.

2. Address of the medical device manufacturer.

3. Permitted items and scope of operations.

Translated by RegDesk AI

四、國內製造者，醫療器材製造業者之管理代表。

五、國外製造者，代理輸入之醫療器材商。

六、許可編號。

七、有效期限。

前項第一款、第二款、第四款及第五款記載事項有變更者，醫療器材製造業者應自事實發生之日起三十日內，填具變更申請書，並檢附附表二所定文件、資料，及繳納費用，向中央主管機關申請變更。

第一項第二款之變更，以門牌整編者為限；涉及遷移者，應依第二條規定重新提出申請。

第一項第三款之變更，其申請及檢查程序，準用第二條及第三條規定。

第二項變更，準用第二條第二項至第四項，及第三條有關複評規定；第二項及前項變更之核定，不延長原有效期限。

第6條

醫療器材製造許可有效期間為三年；有展延必要者，應於期滿六個月前至十二個月間申請；每次展延期間，以三年為限；其申請及檢查程序，得準用第二條及第三條規定。

依前項所定期間申請展延，中央主管機關未於原有效期間內准駁，非可歸責醫療器材製造業者，原製造許可之效力延長至准駁之日。

第7條

中央主管機關人員執行檢查時，應出示身分證明文件及說明檢查目的，並得就違反醫療器材品質管理系統準則規定之行為，為保全證據措施。

第8條

中央主管機關執行本辦法之檢查，必要時，得對產品取樣。

前項取樣為無償，並隨機為之，醫療器材製造業者不得指定樣品；其樣品數量，以足供檢驗所需者為限。

第9條

醫療器材商經中央主管機關實地查核，取得製造許可者，得填具申請書，並檢附下列文件、資料及繳納費用，向中央主管機關申請製造許可證明文件：

一、醫療器材製造許可影本。

二、醫療器材商許可執照影本。

60

4. For domestic manufacturers: management representative of the medical device manufacturer.

5. For foreign manufacturers: medical device traders serving as authorized import agents.

6. License number.

7. Validity period.

If any of the items specified in Subparagraphs 1, 2, 4, and 5 of the preceding paragraph are changed, the medical device manufacturer shall, within thirty days from the date the change occurs, complete an application for change, attach the documents and materials specified in Annex 2, pay the required fees, and submit the application for change to the central competent authority.

Changes to Subparagraph 2 of Paragraph 1 are limited to address consolidation; if it involves relocation, a new application shall be submitted in accordance with Article 2.

For changes to Subparagraph 3 of Paragraph 1, the application and inspection procedures shall be handled in accordance with Articles 2 and 3 mutatis mutandis.

The procedures for changes under Paragraph 2 shall be handled in accordance with Paragraphs 2 to 4 of Article 2, and the relevant review provisions of Article 3; approval for changes under Paragraph 2 and the preceding paragraph shall not extend the original validity period.

Article 6

The validity period for a medical device manufacturing license shall be three years; if extension is required, an application shall be submitted between six to twelve months before expiration; each extension period is limited to three years; the application and inspection procedures may refer to Articles 2 and 3.

If an extension is applied for within the period specified in the preceding paragraph, and the central competent authority does not approve or reject the application within the original validity period for reasons not attributable to the medical device manufacturer, the validity of the original manufacturing license shall be extended until the date of approval or rejection.

Article 7

When personnel of the central competent authority conduct inspections, they shall present identification documents and explain the purpose of the inspection, and may take evidence preservation measures in response to violations of the Medical Device Quality Management System regulations.

Article 8

When the central competent authority conducts inspections under these Regulations, product sampling may be conducted if necessary.

Sampling as described in the preceding paragraph shall be free of charge and done at random; medical device manufacturers may not designate samples; the quantity of samples shall be limited to what is necessary for inspection.

Article 9

Medical device traders who have obtained manufacturing licenses after on-site audit by the central competent authority may fill out an application form, attach the following documents and materials, pay the required fees, and apply to the central competent authority for a certificate of manufacturing license:

1. Copy of the medical device manufacturing license.

2. Copy of the medical device trader's operating license.

Translated by RegDesk AI

第10條

有下列情形之一者，中央主管機關應撤銷或廢止醫療器材製造許可之全部或一部：

一、製造業醫療器材商許可執照，經依法撤銷或廢止。

二、代理輸入者之販賣業醫療器材商許可執照，經依法撤銷或廢止。

三、其他依法應為撤銷或廢止之事由。

第11條

醫療器材商經中央主管機關撤銷或廢止醫療器材製造許可，其領有第九條證明文件，且仍於效期內者，應自受處分之日起十五日內，返還其證明文件；屆期未返還者，註銷之。

第12條

醫療器材商停業時，其領有第九條證明文件，且仍於效期內者，應將該文件繳交直轄市、縣（市）主管機關保管，俟復業時發還。

醫療器材商申准復業後，應依第二條規定申請檢查，經檢查合格後，始得製造。

醫療器材商歇業時，其領有第九條證明文件，且仍於效期內者，應繳銷該文件；未繳銷者，由中央主管機關註銷之。

第13條

本辦法自本法施行之日施行。

61

Article 10

Under any of the following circumstances, the central competent authority shall revoke or annul all or part of a medical device manufacturing license:

1. The medical device dealer’s manufacturing license for manufacturers has been revoked or annulled according to law.

2. The medical device dealer’s distribution license for agents of imported products has been revoked or annulled according to law.

3. Other circumstances where revocation or annulment is required by law.

Article 11

If a medical device dealer has its medical device manufacturing license revoked or annulled by the central competent authority, and is in possession of the certificate specified in Article 9 which is still valid, it shall return the certificate within fifteen days from the date of such disposition; failure to do so by the deadline shall result in cancellation of the certificate.

Article 12

When a medical device dealer suspends business, if it is in possession of the certificate specified in Article 9 which is still valid, it shall submit the certificate to the municipal or county (city) competent authority for safekeeping, to be returned when business resumes.

After receiving approval to resume business, the medical device dealer shall apply for inspection according to Article 2, and may resume manufacturing only after passing inspection.

When a medical device dealer goes out of business, if it is in possession of the certificate specified in Article 9 which is still valid, it shall cancel the certificate; if it fails to cancel the certificate, the central competent authority shall cancel it.

Article 13

These Regulations shall be implemented as of the date of implementation of this Act.

Translated by RegDesk AI

【醫療器材委託製造作業準則】(110.04.15.發布)

第1條

本準則依醫療器材管理法（以下簡稱本法）第二十三條第三項規定訂定之。

第2條

本準則所稱委託製造，指醫療器材商將本法第十條第一款製造、包裝、貼標、滅菌及最終驗放全部程序（以下簡稱全部製程），或將其中製造、滅菌程序委由其他醫療器材製造業者執行之行為。

第3條

醫療器材商申請委託製造者，應填具申請書，並檢附下列文件、資料，及繳納費用後，向中央主管機關提出：

一、委託國內業者製造醫療器材者，其委託者及受託者之醫療器材商執照。

二、委託國外業者製造醫療器材者，其委託者之醫療器材商執照。

三、受託者之醫療器材製造許可。但受委託製造之醫療器材，屬依本法第二十二條第二項規定免取得製造許可之品項者，免附。

四、委託者與受託者簽立之委託製造契約。

前項申請委託製造，得以中央主管機關指定之電子或其他方式為之。

第4條

前條第一項第四款委託製造契約，應載明下列事項：

一、委託者及受託者之名稱及地址。

二、委託製造之合意。

三、委託製造之醫療器材分類分級品項。

四、委託製造之製程。

五、委託者及受託者之權利義務。

第5條

依本法第二十三條規定申請醫療器材委託製造核准，中央主管機關應辦理登記；其登記事項如下：

一、委託者之名稱及地址。

二、受託者之名稱及地址。

三、委託製造之醫療器材品項。

四、委託製造之醫療器材製程。

62

[Regulations for Contract Manufacturing of Medical Devices] (Promulgated on 2021.04.15)

Article 1

These Regulations are enacted pursuant to Article 23, Paragraph 3 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

The term "contract manufacturing" as used in these Regulations refers to the act by which a medical device company entrusts to another medical device manufacturer all procedures stipulated in Article 10, Subparagraph 1 of the Act—manufacturing, packaging, labeling, sterilization, and final release (hereinafter referred to as "all processes"), or entrusts the manufacturing or sterilization processes to another medical device manufacturer.

Article 3

A medical device company applying for contract manufacturing shall fill out an application form, attach the following documents and information, pay the required fees, and submit the application to the central competent authority:

1. Where a domestic entity is entrusted to manufacture the medical device, the medical device business licenses of both the entrusting party and the entrusted party shall be attached.

2. Where a foreign entity is entrusted to manufacture the medical device, the medical device business license of the entrusting party shall be attached.

3. The medical device manufacturing permit of the entrusted party. If the contracted medical device falls under items exempt from the manufacturing permit pursuant to Article 22, Paragraph 2 of the Act, this may be omitted.

4. The contract manufacturing agreement signed by the entrusting and entrusted parties.

Applications for contract manufacturing as set forth in the preceding paragraph may be made via electronic or other means as designated by the central competent authority.

Article 4

The contract manufacturing agreement stipulated in Article 3, Paragraph 1, Subparagraph 4 shall specify the following items:

1. The names and addresses of the entrusting party and the entrusted party.

2. Mutual agreement on contract manufacturing.

3. Classification and category of the medical device subject to contract manufacturing.

4. The manufacturing processes to be contracted.

5. The rights and obligations of the entrusting and entrusted parties.

Article 5

When applying for approval of contract manufacturing of medical devices as prescribed in Article 23 of the Act, the central competent authority shall process registration; the items to be registered are as follows:

1. Name and address of the entrusting party.

2. Name and address of the entrusted party.

3. Items of medical devices subject to contract manufacturing.

Translated by RegDesk AI

4. Manufacturing processes subject to contract manufacturing.

Translated by RegDesk AI

第6條

前條登記事項應通知申請人；登記事項有變更時，委託者應自事實發生之日起三十日內，填具申請書，並檢附第三條所定文件、資料，及繳納費用，向中央主管機關申請變更。

前項申請變更，得以中央主管機關指定之電子或其他方式為之。

第7條

依本準則核准之委託製造，除法律另有規定者外，其產品違反本法規定者，由委託者負責。

第8條

依本準則核准全部製程委託製造之醫療器材，其產品之標籤、說明書或包裝，應刊載委託者及受託者之名稱及地址。但已於查驗登記核准或登錄系統載明者，受託者得以其所在國家、地區或行政區域名稱代之。

第9條

有下列情形之一者，中央主管機關應撤銷或廢止其醫療器材委託製造核准：

一、委託者或受託者之醫療器材商執照，經撤銷或廢止。

二、受託者之醫療器材製造許可，經撤銷或廢止。

三、委託者或受託者提出雙方委託製造關係已不存續。

第10條

本準則自中華民國一百十年五月一日施行。

Article 6

The applicant shall be notified of the registration particulars stipulated in the preceding article; in the event of any changes to the registration particulars, the principal shall, within thirty days from the date the fact occurs, fill out an application form, attach the documents and data specified in Article 3, pay the required fees, and apply to the central competent authority for modification.

The application for modification in the preceding paragraph may be made via electronic or other means as designated by the central competent authority.

Article 7

For contract manufacturing approved in accordance with these Guidelines, unless otherwise provided by law, any product that violates the provisions of this Act shall be the responsibility of the principal.

Article 8

For medical devices for which the entire manufacturing process is contract manufactured and approved in accordance with these Guidelines, the labels, instructions for use, or packaging of the products shall bear the name and address of both the principal and the contractor. However, if such details have already been specified in the product registration approval or registration system, the contractor may instead indicate the name of the country, region, or administrative area in which it is located.

Article 9

Under any of the following circumstances, the central competent authority shall revoke or annul the approval for contract manufacturing of the medical devices:

1. The principal’s or contractor’s medical device business license has been revoked or annulled.

2. The contractor’s medical device manufacturing permit has been revoked or annulled.

3. Either the principal or contractor submits that the contractual manufacturing relationship between the two parties no longer exists.

Article 10

These Guidelines shall be implemented from May 1, 2021 (Republic of China Year 110).

Translated by RegDesk AI

【醫療器材優良運銷準則】(110.04.13發布)

第1條

本準則依醫療器材管理法（以下稱本法）第二十四條第三項規定訂定之。

第2條

本準則有關醫療器材儲存、運輸、服務、人員配置及其他相關作業事項之規範，參照國際標準組織醫療器材品質管理系統（ISO13485：Medical devices-Quality management systems-Requirements for regulatory purposes）之內容訂定。

第3條

販賣業者應以書面建立符合本準則規定之醫療器材優良運銷系統（以下稱運銷系統），並維持其有效性。

販賣業者應決定與執行運銷系統所需之流程，並監控該流程之實施，對運銷系統之相關活動應予以規範及記錄，確保醫療器材於市場流通之品質。

前項流程之訂定、變更，應經實施運銷系統與醫療器材之影響評估，並符合本法及本準則規定，始得為之。

第4條

販賣業者應依其稽核結果、資料分析、矯正與預防措施及管理階層之審查決定，為運銷系統之必要變更，並於變更內容確認後實施，確保並維持運銷系統之適當性、合適性及有效性，及醫療器材安全與性能。

第5條

販賣業者之產品委託其他業者輸入、儲存、運輸、銷售、防護或提供服務時，應就足以影響運銷系統規範符合性者，簽訂委託書面契約，實施監測；相關運銷紀錄之保存，亦同。

販賣業者應採行措施，確保前項委託符合委託書面契約、本準則及其他相關法規之規定。

第6條

運銷系統應建置文件體系，其內容應包括下列事項：

一、品質手冊或同等文件。

二、本準則所定之程序及紀錄。

三、運銷系統流程之規劃、運作、管制所製作之文件及紀錄。

四、其他中央主管機關規定之事項。

64

[Good Distribution Practice Guidelines for Medical Devices] (Promulgated 2021.04.13)

Article 1

These Guidelines are enacted in accordance with Article 24, Paragraph 3 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

The requirements of these Guidelines regarding the storage, transportation, services, personnel allocation, and other related operational matters for medical devices are stipulated with reference to the content of the International Organization for Standardization's Medical Devices Quality Management System (ISO 13485: Medical devices—Quality management systems—Requirements for regulatory purposes).

Article 3

Distributors shall establish in writing a Good Distribution Practice system for medical devices (hereinafter referred to as "distribution system") that complies with the provisions of these Guidelines and maintain its effectiveness.

Distributors shall determine and execute the processes required for the distribution system and monitor the implementation of such processes. Activities related to the distribution system shall be regulated and recorded to ensure the quality of medical devices in market circulation.

The establishment or modification of the aforementioned processes shall be subject to an assessment of the implementation of the distribution system and the impact on medical devices, and shall comply with the Act and these Guidelines prior to execution.

Article 4

Distributors shall implement necessary changes to the distribution system based on audit results, data analysis, corrective and preventive measures, and management review decisions. Changes shall be implemented after confirmation of the content of the adjustments, to ensure and maintain the appropriateness, suitability, and effectiveness of the distribution system, as well as the safety and performance of the medical devices.

Article 5

When a distributor commissions another entity to import, store, transport, sell, provide protection, or render services for its products, a written commission contract shall be signed and monitoring shall be conducted for matters that may affect compliance with the requirements of the distribution system; the retention of related distribution records shall be handled accordingly.

Distributors shall take measures to ensure that the aforementioned commission complies with the written contract, these Guidelines, and other relevant laws and regulations.

Article 6

A documentation system shall be established for the distribution system, the contents of which shall include the following items:

1. Quality manual or equivalent documents.

2. Procedures and records as stipulated by these Guidelines.

3. Documents and records produced for the planning, operation, and control of distribution system processes.

4. Other matters as stipulated by the central competent authority.

Translated by RegDesk AI

第7條

運銷系統之文件，應予管制。

前項管制程序，應以書面為之；其內容包括下列事項：

一、文件發布及下達前之審查、核定及人員之簽章、日期；其修正，亦同。

二、運銷系統文件總覽表之建立。

三、版次及變更歷程與狀態之辨識確認。

四、個別場所應適用文件之備置情形。

五、文件版次及內容易讀性之確認。

六、必要外部原始文件有效性之確認，及該文件分發之管制。

七、文件毀損或滅失之預防。

八、失效文件之辨識確認及誤用預防措施。

販賣業者應明定失效文件之保存期限，確保於醫療器材有效期間內，得取得其運銷之資料，並不得少於本法相關規定之期限。

第8條

販賣業者應建立及維持運銷系統紀錄之書面管制程序；其內容包括紀錄之鑑別、儲存、保全、檢索、處理及保存期限。

販賣業者應依個人資料保護法之規定，訂定並執行紀錄內機敏健康資訊之保護措施。

第一項紀錄之保存期限，應不少於醫療器材有效期間，且不得少於產品自製造業者放行之日起三年。但本法相關規定較長者，從其規定。

第9條

販賣業者應就運銷系統置管理代表一人，由最高管理階層指派之。

前項管理代表之職責，應以書面訂定下列事項：

一、確認業以書面建立運銷系統流程。

二、向最高管理階層提出運銷系統有效性確認及必要改進之報告。

三、促進與確保全體組成員對相關法規及客戶要求之認知，並具適當之能力及經驗，包括職前及在職訓練計畫之執行及維持。

四、協調及執行醫療器材之回收作業。

管理代表應置適任之職務代理人或被授權人，確保運銷系統之執行及維持符合本準則之規定。

第10條

販賣業者應就運銷系統，以書面訂定管理階層審查程序；其內容包括第十一條所定事項之運銷系統變更或改進之評估。

Article 7

The documents of the distribution system shall be subject to control.

The control procedures in the preceding paragraph shall be conducted in writing and shall include the following matters:

1. Review, approval, personnel signatures, and dates prior to issuance and distribution of documents; the same applies to any amendments.

2. Establishment of a master list of distribution system documents.

3. Identification and confirmation of version, change history, and current status.

4. Preparation status of applicable documents at each individual location.

5. Confirmation of document version and content readability.

6. Confirmation of the validity of necessary external original documents and control over their distribution.

7. Prevention of document damage or loss.

8. Identification and confirmation of obsolete documents and preventive measures against misuse.

Sellers shall clearly specify the retention period for obsolete documents to ensure that distribution data can be obtained during the effective period of the medical device, and the retention period shall not be less than the period specified by relevant laws and regulations.

Article 8

Sellers shall establish and maintain written control procedures for distribution system records, including identification, storage, protection, retrieval, handling, and retention periods of the records.

Sellers shall, in accordance with the Personal Data Protection Act, formulate and implement protection measures for sensitive health information contained in the records.

The retention period for the records in the first paragraph shall not be less than the effective period of the medical device, and not less than three years from the date the product is released by the manufacturer. However, where relevant laws and regulations prescribe a longer period, such provisions shall prevail.

Article 9

Sellers shall appoint one management representative for the distribution system, designated by the highest management level.

The duties of the management representative in the preceding paragraph shall be specified in writing and shall include the following matters:

1. Confirm that the distribution system processes have been established in writing.

2. Report to the highest management level on the effectiveness confirmation and necessary improvement of the distribution system.

3. Promote and ensure that all members are aware of relevant regulations and customer requirements, and possess appropriate competence and experience, including implementation and maintenance of pre-service and on-the-job training programs.

4. Coordinate and execute the recall operations of medical devices.

A suitable deputy or authorized person for the management representative shall be assigned to ensure the implementation and maintenance of the distribution system in compliance with the requirements of these Guidelines.

Translated by RegDesk AI

Article 10

Sellers shall establish, in writing, the management review procedures for the distribution system, the content of which shall include the evaluation of distribution system changes or improvements as specified in Article 11.

Translated by RegDesk AI

最高管理階層應依前項程序之規定，定期審查運銷系統，確保其適當性、合適性及有效性；其審查，應製作紀錄及保存。

前項紀錄，其內容應包括下列事項：

一、審查之事項及其內容。

二、為維持運銷系統及其流程適當性、合適性與有效性，必要之改進措施。

三、因應客戶要求有關流程之改進措施。

四、配合法令增修之因應措施。

五、執行前三款措施之資源需求。

第11條

前條第二項審查之事項如下：

一、對產品或服務之意見或評論。

二、客戶申訴之處理。

三、對中央主管機關之報告。

四、內部或外部稽核之結果。

五、流程與產品之監管、量測及其結果。

六、矯正措施。

七、預防措施。

八、前次審查結論之後續處置。

九、可能影響運銷系統之變更。

十、改進作為之建議。

十一、配合法令增修之因應措施。

第12條

從事影響運銷品質工作之人員，應具一定之技能或經驗，或接受適當之教育及訓練，確保可勝任其工作。

販賣業者就人員能力之建立、必要訓練之提供及職責正確認知之確保，應以書面訂定下列事項之程序：

一、從事影響運銷品質之工作人員能力之認定，包括產品之放行。

二、維持人員能力必要訓練或其他措施之提供。

三、前款訓練或措施，應包括其有效性之評估與醫療器材之識別，以避免不良醫材進入供應鏈。

四、人員教育、訓練、技能及經驗之證明或紀錄，應製作紀錄並保存。

66

Top management shall, in accordance with the procedures specified in the preceding paragraph, periodically review the distribution system to ensure its adequacy, suitability, and effectiveness; records of such reviews shall be made and retained.

Records from the preceding paragraph shall include the following items:

1. Matters reviewed and their content.

2. Necessary improvement measures to maintain the adequacy, suitability, and effectiveness of the distribution system and its processes.

3. Improvement measures for processes in response to customer requirements.

4. Responsive measures to adapt to revisions in laws and regulations.

5. Resource requirements for implementing the measures specified in the preceding three items.

Article 11

The matters to be reviewed as specified in Paragraph 2 of the preceding article are as follows:

1. Opinions or comments regarding products or services.

2. Handling of customer complaints.

3. Reports to the central competent authority.

4. Results from internal or external audits.

5. Monitoring, measurement, and results related to processes and products.

6. Corrective actions.

7. Preventive actions.

8. Follow-up handling of previous review conclusions.

9. Changes that may affect the distribution system.

10. Suggestions for improvement actions.

11. Responsive measures to adapt to revisions in laws and regulations.

Article 12

Personnel engaged in work that affects the quality of distribution shall possess appropriate skills or experience, or receive adequate education and training, to ensure their competence in performing their duties.

Distributors shall establish written procedures regarding the following matters to ensure the establishment of personnel competence, the provision of necessary training, and correct awareness of responsibilities:

1. The identification of competence for personnel engaged in work affecting distribution quality, including product release.

2. The provision of necessary training or other measures to maintain personnel competence.

3. The training or measures stated in the preceding item shall include evaluations of their effectiveness and identification of medical devices, in order to prevent defective devices from entering the supply chain.

4. Records or proof of personnel education, training, skills, and experience shall be made and retained.

Translated by RegDesk AI

第13條

販賣業者應就運銷系統，以書面訂定基礎設施之條件，並應符合產品要求，避免產品混淆及其處理失序。

前項設施，應包括儲存、作業場所、運輸車、冷藏（凍）庫，及工作環境管制、監控與量測所用設備。

第一項設施之維護、確效及校正，應以書面訂定其內容、方式及頻率，並製作紀錄及保存；其內容包括下列事項：

一、確保用於運輸、儲存或處理醫療器材之車輛及設備符合產品之規格，且裝備適當。

二、儲存區於開始使用前進行初步之溫度測繪及風險評估，並依其評估結果放置溫度監測器。

三、對於溫度敏感之醫療器材，應使用確效後之設備進行監控；其證明或使用許可，由適當人員開立及核准。

四、建立設備非預期失序之立即處置程序，維持醫療器材品質。

第14條

販賣業者應就運銷系統，以書面訂定工作環境規範；其訂定應考量溫度、濕度及其他外部有害因素，並應予以監控及管制。

前項規範之內容，應包括下列事項：

一、人員與產品或作業環境之接觸，足以影響醫療器材安全或性能者，其人員健康、清潔及服裝條件。

二、工作環境應保持清潔，防止昆蟲或動物入侵。

三、員工之休息室、盥洗室及飲食區，應與儲存區為適當之區隔，並禁止於儲存區存放食物、飲料、菸品或個人使用之醫療器材。

第15條

販賣業者應就運銷系統，以書面訂定下列客戶溝通事項：

一、產品資訊及運銷條件。

二、客戶詢問、合約或訂單之處理及修改。

三、申訴及其他客戶回饋。

四、建議性通告。

第16條

販賣業者應就運銷系統，以書面訂定採購產品符合使用者要求之確認程序，避免不良醫療器材進入合法供應鏈。

販賣業者應訂定評估及選擇供應商基準；其訂定應考量之因素如下：

Article 13

Distributors shall establish in writing the conditions of infrastructure for the distribution system, and these must meet product requirements to avoid product confusion and process disorder.

The facilities referred to in the preceding paragraph shall include storage, operating areas, transport vehicles, refrigeration (freezer) storage, as well as equipment for control, monitoring, and measurement of the working environment.

The maintenance, verification, and calibration of the facilities referred to in Paragraph 1 shall be documented in terms of their content, methods, and frequency, and records shall be produced and preserved. The content shall include the following:

1. Ensuring that vehicles and equipment used for transport, storage, or handling of medical devices conform to product specifications and are properly equipped.

2. Conducting initial temperature mapping and risk assessment for storage areas before they are put into use, and placing temperature monitoring devices according to the assessment results.

3. Using verified equipment for monitoring temperature-sensitive medical devices; certification or usage approval shall be issued and approved by appropriate personnel.

4. Establishing immediate response procedures for unexpected equipment malfunctions to maintain the quality of medical devices.

Article 14

Distributors shall establish, in writing, working environment standards for the distribution system; these standards shall consider temperature, humidity, and other harmful external factors, all of which shall be monitored and controlled.

The contents of the standards in the preceding paragraph shall include the following:

1. Health, hygiene, and attire requirements for personnel whose contact with products or the working environment may affect the safety or performance of medical devices.

2. The working environment shall be kept clean to prevent insect or animal infestation.

3. Employee lounges, restrooms, and dining areas shall be properly separated from storage areas; storing food, drinks, tobacco, or medical devices for personal use in storage areas is prohibited.

Article 15

Distributors shall establish, in writing, the following customer communication matters for the distribution system:

1. Product information and distribution conditions.

2. Handling and modification of customer inquiries, contracts, or orders.

3. Complaints and other customer feedback.

4. Advisory notices.

Article 16

Distributors shall establish, in writing, procedures to confirm that procured products meet user requirements in the distribution system, in order to prevent substandard medical devices from entering the legitimate supply chain.

Distributors shall establish criteria for evaluating and selecting suppliers; the factors to be considered in establishing such criteria are as follows:

Translated by RegDesk AI

一、供應商具有提供販賣業者所需產品規格之能力。

二、供應商過往之實績及法規遵從性。

販賣業者應規劃監控及再評估供應商之機制，確保管控產品符合採購要求，並作為再評估之參考。

販賣業者發現供應商有未符合採購要求者，應採取退貨或其他必要之措施。

前三項之評估、選擇、監控、再評估及必要措施，應製作紀錄並保存。

第17條

前條採購所需資訊，應包括下列事項，並以書面或其他可索引方式查閱：

一、產品規格。

二、產品取得之允收、程序、流程及設備。

三、供應商之資格要求。

四、運銷系統符合本準則規定。

販賣業者應於接洽供應商前，確定採購資訊完整適當；必要時，販賣業者應以書面約定供應商於實施影響採購資訊變更前，先行通知販賣業者。

販賣業者應依第十八條有關追溯性之規定，保存有關採購資訊之文件、資料及紀錄。

第18條

販賣業者應就運銷系統，以書面訂定產品來源及流向之追溯程序；其內容包括產品追溯之範圍及紀錄。

前項紀錄，應包括醫療器材名稱、批號、接收日期與數量、保存期限、供應商名稱、收貨人名稱、地址與連絡人、送貨地址、運送方式及允收溫度條件；以包裹運輸寄送者，並應包括收貨人之姓名及收貨地址憑證。

第一項之紀錄，應予保存。

第19條

販賣業者應就運銷系統，依產品要求，以書面訂定防護程序，確保產品之品質不受儲存、搬運或運輸過程之影響。

為避免產品暴露於可預期之危害狀態，前項過程有改變、污染或損壞醫療器材之虞者，販賣業者應實施下列事項：

一、提供合適之包裝及運送容器。

二、前款包裝或容器於特定情況下，無法提供足夠保護者，以書面訂定特別之附加條件；該條件應予管制並記錄。

三、收貨區及出貨區應有適當之措施，保護醫療器材免於受到氣候之影響。

68

1. The supplier shall possess the capability to provide products conforming to the specifications required by the distributor.

2. The supplier's past performance and regulatory compliance.

Distributors shall establish mechanisms for monitoring and re-evaluating suppliers to ensure that controlled products meet procurement requirements, which shall also serve as references for re-evaluation.

If a distributor discovers that a supplier fails to meet procurement requirements, it shall take measures such as returning the goods or other necessary actions.

Documentation and records shall be made and retained regarding the assessment, selection, monitoring, re-evaluation, and necessary measures mentioned in the preceding three paragraphs.

Article 17

The procurement information referenced in the preceding Article shall include the following items and be available in written or other retrievable forms:

1. Product specifications.

2. Acceptance criteria, procedures, processes, and equipment for acquiring the product.

3. Supplier qualification requirements.

4. The distribution system's compliance with the provisions of these Guidelines.

Distributors shall confirm the completeness and appropriateness of procurement information before engaging with suppliers; when necessary, distributors shall agree in writing that suppliers notify them in advance of implementing changes affecting procurement information.

Distributors shall, in accordance with Article 18 concerning traceability, retain documents, data, and records related to procurement information.

Article 18

Distributors shall, in writing, establish traceability procedures for the source and flow of products within the distribution system; such procedures shall include the scope of product traceability and record-keeping.

The records in the preceding paragraph shall include the name of the medical device, batch number, date and quantity received, shelf life, name of supplier, name of recipient, address and contact person, delivery address, mode of transportation, and accepted temperature conditions; for items delivered by parcel shipment, the recipient's name and proof of delivery address shall also be included.

Records mentioned in Paragraph 1 shall be retained.

Article 19

Distributors shall, according to product requirements and in writing, establish protective procedures for the distribution system to ensure product quality is not affected during storage, handling, or transportation.

To prevent products from being exposed to foreseeable hazardous conditions, in cases where there is a risk of alteration, contamination, or damage to the medical device during such processes, the distributor shall implement the following:

1. Provide suitable packaging and shipping containers.

Translated by RegDesk AI

2. If adequate protection cannot be provided by such packaging or containers under specific circumstances, special additional conditions shall be set in writing; such conditions shall be controlled and recorded.

3. Receiving and dispatch areas shall have appropriate measures to protect medical devices from climatic influences.

Translated by RegDesk AI

四、進貨區、出貨區及儲存區應予適當區隔；接近有效期限或保存期限之醫療器材，立即從可銷售品庫移開。

五、醫療器材不得直接存放於地板上。

第20條

販賣業者應就運銷系統，以書面訂定足資證明產品符合性之監管及量測作業，並備有執行作業必要之相關設備。

前項量測設備之使用，應符合下列規定：

一、使用前，以明確之國際或國家標準校正或查證；無明確標準者，記錄所使用之校正或查證基礎。設備啟用後，亦應定期為之。

二、校正或查證後，予以必要之調整，避免導致量測結果不正確。

三、校正狀態予以標示。

四、搬運、維護或儲存時，採避免損壞或變質之措施。

五、訂定環境監管及量測用電腦軟體合適性之確效程序，並於軟體使用前，或依實際狀況，於使用後或軟體變更時，完成確效。

六、前款電腦軟體失效、當機、修復及數據備份之程序，應予規範。

販賣業者應依第一項作業規定，執行校正、查證或調整，並製作紀錄及保存。

第一項設備未依第二項規定辦理者，販賣業者應對量測結果進行有效性評估，且記錄之；對受影響之產品，並應採取適當措施。

第21條

販賣業者應就運銷系統，以書面訂定客戶要求符合性之資訊蒐集及使用方法；其內容應包括運銷活動資訊之彙整，並辦理運銷系統有效性之評估。

第22條

除有正當理由外，販賣業者應就客戶申訴之內容予以調查，查明其是否為醫療器材品質或運銷原因所致；販賣業者應將調查結果或所採行之改善措施，依個案情形，提供予相關機關或機構。

前項申訴內容，調查經過、結果與提供對象或所採行之改善措施，應製作紀錄並保存。

第23條

販賣業者應就本法第四十八條第一項之通報、第四十九條之通報、採取矯正預防措施及第五十八條第一項之通知、依規定限期回收處理，訂定作業程序，並應每年評估醫療器材回收作業之有效性。

前項通報、採取矯正措施及回收處理，應製作紀錄並保存。

4. The receiving area, shipping area, and storage area shall be properly separated; medical devices that are approaching their expiration or shelf life shall be immediately removed from the saleable inventory.

5. Medical devices must not be stored directly on the floor.

Article 20

Distributors shall, in writing, establish supervisory and measurement procedures for the distribution system that are sufficient to demonstrate product conformity, and shall be equipped with the necessary related equipment for operations.

The use of measurement equipment referred to in the preceding paragraph shall comply with the following requirements:

1. Prior to use, the equipment shall be calibrated or verified against clear international or national standards; where clear standards are not available, a record of the basis used for calibration or verification shall be made. Regular calibration or verification shall also be performed after the equipment is put into operation.

2. Necessary adjustments shall be made after calibration or verification to prevent incorrect measurement results.

3. The calibration status shall be indicated.

4. Measures shall be taken during transportation, maintenance, or storage to prevent damage or deterioration.

5. Procedures for the validation of the suitability of environmental monitoring and measurement computer software shall be established, and validation shall be performed before the software is used, or depending on actual circumstances, after use or upon any software changes.

6. Procedures for dealing with computer software failures, crashes, repairs, and data backup as mentioned in the preceding paragraph shall be specified.

Distributors shall implement calibration, verification, or adjustment in accordance with the operational procedures set out in Paragraph 1, make records, and retain them.

If the equipment referred to in Paragraph 1 does not comply with the provisions of Paragraph 2, the distributor shall conduct a validity assessment of the measurement results and keep records thereof; appropriate measures shall also be taken regarding products that are affected.

Article 21

Distributors shall, in writing, establish methods for the collection and use of information on conformity with customer requirements in the distribution system; such documentation shall include collation of information on distribution activities, and an evaluation of the effectiveness of the distribution system shall be conducted.

Article 22

Unless there is a legitimate reason, distributors shall investigate customer complaints to determine whether the cause is attributable to the quality of medical devices or distribution reasons; the results of the investigation or any corrective measures taken by the distributor shall, depending on the case, be provided to the relevant authorities or organizations.

Records of the contents of the complaints, investigation process, results and parties provided with such information or corrective measures taken as described in the preceding paragraph shall be prepared and retained.

Article 23

Translated by RegDesk AI

Distributors shall establish procedures with respect to the reporting stipulated in Paragraph 1, Article 48, reporting stipulated in Article 49, implementation of corrective and preventive actions, notification under Paragraph 1, Article 58 of this Act, and recall handling within the prescribed time, and shall annually assess the effectiveness of medical device recall operations.

Records of the aforementioned reporting, implementation of corrective measures, and recall handling shall be prepared and retained.

Translated by RegDesk AI

第24條

販賣業者應定期執行內部稽核，確認運銷系統之有效性及法規遵從性。

販賣業者應以書面訂定前項稽核之程序；其內容包括下列事項：

一、與稽核之規劃、執行、記錄及稽核結果報告有關之權責劃分與要求。

二、考量稽核對象、項目、內容、地點、運銷系統內各流程之重要性及先前稽核之結果，訂定稽核計畫。

三、稽核基準、範圍、頻率、方法及紀錄；稽核員不得稽核其本人職掌之工作。

管理階層就第一項稽核結果不符合者，應探討其發生原因，提出矯正措施，及時予以矯正，並去除不符合事項。

稽核員應就前項矯正措施之執行內容及結果，提出查證報告。

第一項稽核之流程、場所及結果，應製作紀錄並保存。

第25條

販賣業者應鑑別及管制不符合要求之產品，防止非預期之使用或交貨。

販賣業者為符合前項之要求，應就不符合原製造業者要求之產品，以書面訂定鑑別、記錄、區隔、評估、廢棄之管制及權責界定程序。

販賣業者應將第一項之不符合情況，及後續採行之評估、調查與決策形成理由，製作紀錄並保存。

第26條

販賣業者對前條不符合要求之產品，應視情節，分別或同時採行下列處理方式：

一、去除不符合要求情況之措施。

二、預防不符合要求產品作為原預定目的使用或應用之措施。

三、以特殊採用方式為產品之使用、放行或允收。

販賣業者採前項第三款處理方式者，應具正當理由及符合法令規定，並經權責人員核准後，始得為之；核准者之姓名及職稱，應製作紀錄並保存。

第27條

產品放行後，發現有前條不符合要求產品者，販賣業者應就其影響或潛在影響採取適當措施，並應製作紀錄及保存。

販賣業者應依製造業者之規定或要求，以書面訂定建議性通告之發布程序。

第一項已放行產品之退回品，應與合格產品區隔，經原製造廠或其授權者之評估，可證明產品完整性，且經權責人員核准後，得為產品之允收及再放行

Article 24

Distributors shall conduct internal audits periodically to verify the effectiveness and regulatory compliance of the distribution system.

Distributors shall establish written procedures for the aforementioned audit; the content shall include the following:

1. Division of authority and responsibilities and requirements related to the planning, execution, recording, and reporting of audit results.

2. Considering the audit targets, items, content, locations, the importance of each process within the distribution system, and results of previous audits, an audit plan shall be established.

3. Audit criteria, scope, frequency, methods, and records; auditors shall not audit work under their own purview.

For any non-conformities found in the audit results under Paragraph 1, management shall investigate the cause, propose corrective actions, implement corrections in a timely manner, and eliminate the non-conformities.

Auditors shall submit a verification report regarding the implementation and results of the corrective actions in the preceding paragraph.

The processes, locations, and results of the audits under Paragraph 1 shall be documented and retained.

Article 25

Distributors shall identify and control non-conforming products to prevent unintended use or delivery.

To comply with the preceding requirement, for products that do not meet the requirements of the original manufacturer, distributors shall establish written procedures for identification, recording, segregation, evaluation, and disposal, as well as for the delineation of authority and responsibilities.

Distributors shall document and retain records of the non-conformances described in Paragraph 1, as well as subsequent evaluations, investigations, decision-making, and the justifications for such decisions.

Article 26

Distributors, regarding non-conforming products as referred to in the preceding article, shall, based on circumstances, adopt one or more of the following measures:

1. Actions to eliminate the non-conformance.

2. Actions to prevent the use of non-conforming products for their originally intended purposes or applications.

3. Special approval procedures for use, release, or acceptance of the product.

If the distributor adopts the third measure listed in the preceding paragraph, it shall be based on legitimate reasons and compliance with legal requirements, and may proceed only after approval by authorized personnel; the name and job title of the approving personnel shall be documented and retained.

Article 27

If non-conforming products as described in the preceding article are discovered after product release, distributors shall take appropriate actions regarding the impact or potential impact, and shall document and retain such records.

Translated by RegDesk AI

Distributors shall, in accordance with the manufacturer’s regulations or requirements, establish written procedures for issuing advisory notices.

Returned products previously released under Paragraph 1 shall be segregated from conforming products, and may only be accepted and re-released as products upon assessment by the original manufacturer or its authorized agent to verify product integrity and with the approval of authorized personnel.

Translated by RegDesk AI

。核准者之姓名及職稱，應製作紀錄並保存。

前項允收及再放行之產品，應遵守先到期先出原則，以確保揀選出正確且有適當架儲期之醫療器材，有特殊情形未能遵守者，應製作紀錄。

第28條

販賣業者應採取矯正措施，去除產品或運銷系統不符合事項之發生原因，防止其再發生。

前項矯正措施之實施，不得無故遲延；其措施內容之訂定，應以不符合事項之影響程度為依據。

為實施第一項矯正措施，販賣業者應以書面訂定下列事項之程序：

一、客戶申訴及其他不符合事項之審查。

二、不符合事項原因之判定。

三、矯正措施採行與否之評估。

四、矯正措施之規劃、訂定、實施，及運銷系統文件之必要更新。

五、矯正措施無牴觸法規，及不減損醫療器材安全與性能之查證。

六、矯正措施實施情形及其有效性之審查。

販賣業者應就第一項不符合事項所為之調查及矯正措施實施結果，製作紀錄並保存。

第29條

販賣業者應採取預防措施，去除潛在產品或運銷系統不符合事項之可能發生原因。

前項預防措施之訂定，應以潛在不符合事項之影響程度為依據。

為實施第一項預防措施，販賣業者應以書面訂定下列事項之處理程序：

一、潛在不符合事項及其可能發生原因之判定。

二、預防措施採行與否之評估。

三、預防措施之規劃、訂定、實施，及運銷系統文件之必要更新。

四、預防措施無牴觸法規，及不減損醫療器材安全與性能之查證。

五、預防措施實施情形及其有效性之審查。

販賣業者應就第一項所為之潛在不符合事項調查及預防措施實施結果，製作紀錄並保存。

第30條

本準則自中華民國一百十年五月一日施行。

71.

The name and title of the person granting approval shall be recorded and retained.

The products received and re-released in accordance with the preceding paragraph shall comply with the first-expiry-first-out (FEFO) principle to ensure the correct selection of medical devices with appropriate storage periods. In special circumstances where compliance is not possible, a record shall be made.

Article 28

Distributors shall take corrective actions to eliminate the causes of nonconformities in products or distribution systems and to prevent their recurrence.

The implementation of the corrective actions in the preceding paragraph shall not be unduly delayed; the content of such actions shall be determined based on the severity of the impact of the nonconformities.

To implement the corrective actions in Paragraph 1, distributors shall establish in writing the procedures for the following matters:

1. Review of customer complaints and other nonconformities.

2. Determination of the causes of nonconformities.

3. Evaluation of whether to adopt corrective actions.

4. Planning, formulation, implementation of corrective actions, and necessary updates to distribution system documents.

5. Verification that corrective actions do not violate regulations and do not compromise the safety and performance of the medical devices.

6. Review of the implementation status and effectiveness of corrective actions.

Distributors shall prepare and retain records of the investigations of nonconformities and the results of corrective actions taken pursuant to Paragraph 1.

Article 29

Distributors shall take preventive actions to eliminate potential causes of possible nonconformities in products or distribution systems.

The determination of preventive actions in the preceding paragraph shall be based on the degree of impact of the potential nonconformities.

To implement the preventive actions in Paragraph 1, distributors shall establish in writing the handling procedures for the following matters:

1. Determination of potential nonconformities and their possible causes.

2. Evaluation of whether to adopt preventive actions.

3. Planning, formulation, implementation of preventive actions, and necessary updates to distribution system documents.

4. Verification that preventive actions do not violate regulations and do not compromise the safety and performance of medical devices.

5. Review of the implementation status and effectiveness of preventive actions.

Distributors shall prepare and retain records of the investigations of potential nonconformities and the results of preventive actions implemented pursuant to Paragraph 1.

Article 30

Translated by RegDesk AI

These Regulations shall be enforced from May 1, 2021.

Translated by RegDesk AI

【醫療器材優良運銷檢查及運銷許可核發辦法】(110.01.29發布)

第1條

本辦法依醫療器材管理法（以下稱本法）第二十四條第三項規定訂定之。

第2條

醫療器材販賣業者依本法第二十四條第二項規定申請醫療器材運銷許可（以下稱運銷許可）者，應填具申請書，檢附相關文件、資料，並繳納費用後，向中央主管機關提出。

前項應檢附之相關文件、資料內容如下：

一、醫療器材商許可執照影本。

二、文件總覽表。

三、品質手冊或同等文件。

四、申請檢查場所之平面圖，包括標明動線之儲存、進出貨及其他相關作業場所。

五、運銷流程圖，包括委託作業。

六、其他相關文件、資料。

前項申請文件、資料，有欠缺而得補正者，中央主管機關得通知其限期補正；屆期未補正者，不予受理。

第一項申請書應以中文或英文記載；文件、資料非以中文或英文記載者，應另附中文或英文譯本。

第3條

中央主管機關受理前條申請後，應進行醫療器材優良運銷系統之檢查，經認定符合醫療器材優良運銷準則規定者，核發運銷許可；未符合者，於收受通知之日起二個月內，得申請複評，並以一次為限。

醫療器材販賣業者收受前項未符合規定之通知後不服者，或依前項規定申請複評經駁回者，得依法提起訴願。

第4條

運銷許可，應記載下列事項：

一、醫療器材販賣業者名稱。

二、醫療器材販賣業者地址。

三、作業內容。

四、醫療器材貯存場所。

五、許可編號。

六、有效期限。

72

Regulations for Good Distribution Practice Inspection and Issuance of Distribution Permit for Medical Devices (Promulgated on January 29, 2021)

Article 1

These Regulations are enacted pursuant to Article 24, Paragraph 3 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

Medical device distributors applying for a medical device distribution permit (hereinafter referred to as "distribution permit") in accordance with Article 24, Paragraph 2 of the Act shall complete an application form, attach related documents and materials, and pay the prescribed fees before submitting the application to the central competent authority.

The documents and materials required to be attached to the preceding paragraph are as follows:

1. A copy of the medical device business license.

2. A document checklist.

3. A quality manual or equivalent document.

4. A floor plan of the premises to be inspected, including the layout with marked flow lines for storage, inbound and outbound goods, and other relevant operations areas.

5. A distribution flowchart, including outsourced operations.

6. Other relevant documents and materials.

If the documents and materials of the preceding paragraph are incomplete but may be supplemented, the central competent authority may notify the applicant to make corrections within a specified period; failure to make corrections by the deadline will result in the application not being accepted.

The application prescribed in Paragraph 1 shall be written in either Chinese or English; if the documents and materials are not in Chinese or English, a Chinese or English translation shall be attached.

Article 3

After receiving the application mentioned in the preceding article, the central competent authority shall conduct an inspection of the medical device good distribution practice system. Those found compliant with the Medical Devices Good Distribution Practice Guidelines shall be issued a distribution permit; those not in compliance may apply for a reassessment within two months from the date of receipt of notification, limited to one time only.

If a medical device distributor does not accept the notification of non-compliance or if the reassessment application pursuant to the preceding paragraph is rejected, an administrative appeal may be filed in accordance with the law.

Article 4

The distribution permit shall specify the following particulars:

1. Name of the medical device distributor.

2. Address of the medical device distributor.

3. Nature of operations.

4. Medical device storage locations.

Translated by RegDesk AI

5. Permit number.

6. Validity period.

Translated by RegDesk AI

前項第一款及第二款記載事項有變更者，醫療器材販賣業者應自事實發生之日起三十日內，填具變更申請書，並檢附運銷許可影本、已完成變更之醫療器材商許可執照影本及繳納費用後，向中央主管機關申請變更。

前項變更，原有效期限不予延長。

第一項第三款及第四款之變更，其申請及檢查程序，準用前二條規定。

第5條

運銷許可有效期間為三年；有展延必要者，應於期滿六個月前至十二個月間申請，每次展延期間，以三年為限；其展延申請及檢查程序，得準用第二條、第三條規定。

依前項所定期間申請展延，中央主管機關未於原有效期間內准駁，非可歸責醫療器材販賣業者，原運銷許可之效力延長至准駁之日。

第6條

中央主管機關得不經通知，不定期至醫療器材販賣業者作業場所進行檢查。

第7條

中央主管機關執行本辦法之檢查時，得通知直轄市、縣（市）主管機關派員參加。

檢查人員依本辦法執行檢查時，應出示身分證明文件及說明檢查目的，並得就違反本法或醫療器材優良運銷準則規定之行為，為保全證據措施。

第8條

醫療器材販賣業者取得運銷許可者，得填具申請書，並檢附運銷許可影本、醫療器材商許可執照影本及繳納費用後，向中央主管機關申請醫療器材運銷許可證明書（以下稱運銷許可證明書）。

第9條

醫療器材商許可執照經依法撤銷或廢止者，中央主管機關應撤銷或廢止其運銷許可。

醫療器材商領有運銷許可證明書者，應自受前項處分之日起十五日內，返還其證明書；屆期未返還者，中央主管機關應予註銷。

第10條

前條以外，醫療器材販賣業者經中央主管機關依本法撤銷或廢止其運銷許可之全部或一部，其領有運銷許可證明書者，應自受處分之日起十五日內，返還其證明書；屆期未返還者，中央主管機關應予註銷。

73

If there are any changes to the details specified in Subparagraphs 1 and 2 of the preceding paragraph, the medical device distributor shall, within thirty days from the date the fact occurs, complete a change application form and attach copies of the distribution permit, the modified medical device business license, and the payment receipt, and apply to the central competent authority for the change.

The validity period shall not be extended due to the change in the preceding paragraph.

For changes to Subparagraphs 3 and 4 of Paragraph 1, the application and inspection procedures shall mutatis mutandis apply to the provisions of the preceding two articles.

Article 5

The validity period of the distribution permit is three years; if extension is necessary, an application shall be submitted between six months to twelve months before expiration, and each extension shall be limited to three years. The extension application and inspection procedures may mutatis mutandis apply to Articles 2 and 3.

If the extension is applied for within the period prescribed in the preceding paragraph, and the central competent authority has not rendered a decision by the original validity expiration date due to non-attributable reasons to the medical device distributor, the effectiveness of the original distribution permit shall be extended until the day a decision is rendered.

Article 6

The central competent authority may, without prior notice and at irregular intervals, conduct inspections at the operational sites of medical device distributors.

Article 7

When the central competent authority conducts inspections pursuant to these Regulations, it may notify the competent authority of the municipality, county (city) to assign personnel to participate.

Inspection personnel conducting inspections pursuant to these Regulations shall present identification documents, explain the purpose of the inspection, and may take measures to preserve evidence regarding acts in violation of this Act or the Good Distribution Practice Guidelines for Medical Devices.

Article 8

A medical device distributor who has obtained a distribution permit may, by completing an application form and attaching copies of the distribution permit, the medical device business license, and the payment receipt, apply to the central competent authority for a Medical Device Distribution Permit Certificate (hereinafter referred to as the Distribution Permit Certificate).

Article 9

If a medical device business license is revoked or repealed in accordance with the law, the central competent authority shall revoke or repeal its distribution permit.

A medical device business that holds a Distribution Permit Certificate shall, within fifteen days from the date of the preceding disposition, return the certificate; if the certificate is not returned within the prescribed period, the central competent authority shall cancel it.

Article 10

Translated by RegDesk AI

In cases other than the preceding article, where the central competent authority revokes or repeals all or part of a medical device distributor's distribution permit according to this Act, a holder of a Distribution Permit Certificate shall, within fifteen days from the date of disposition, return the certificate; if the certificate is not returned within the prescribed period, the central competent authority shall cancel it.

Translated by RegDesk AI

第11條

醫療器材販賣業者依本法第十六條第一項規定繳交醫療器材商許可執照及醫療器材許可證時，應一併繳交運銷許可、運銷許可證明書至直轄市、縣（市）主管機關保管；復業時，發還之。

醫療器材販賣業者依本法第十六條第三項規定繳銷醫療器材商許可執照及醫療器材許可證時，應一併繳銷運銷許可、運銷許可證明書；未繳銷者，由中央主管機關註銷之。

第12條

本辦法自本法施行之日施行。

74

Article 11

When medical device dealers submit their Medical Device Dealer Permit and Medical Device License in accordance with Article 16, Paragraph 1 of this Act, they shall also submit their Distribution Permit and Distribution Permit Certificate to the competent municipal or county (city) authority for safekeeping; the aforementioned documents will be returned upon resumption of business.

When medical device dealers cancel their Medical Device Dealer Permit and Medical Device License in accordance with Article 16, Paragraph 3 of this Act, they shall also cancel their Distribution Permit and Distribution Permit Certificate; if they fail to do so, the central competent authority shall revoke them.

Article 12

These Regulations shall come into force from the date the Act comes into effect.

Translated by RegDesk AI

【醫療器材許可證核發與登錄及年度申報準則】(112.11.27修正)

第一章　總則

第1條

本準則依醫療器材管理法（以下簡稱本法）第二十九條規定訂定之。

第2條

本準則用詞，定義如下：

一、出產國許可製售證明：指由輸入醫療器材產製國最高衛生機關或機構，出具許可該醫療器材於該國製造及自由販賣之證明文件。

二、國外原廠授權登記書：指由輸入醫療器材原國外製造業者出具授權代理之證明文件。

三、體外診斷醫療器材（In Vitro Diagnostic Device, IVD）：指蒐集、處理或檢查取自人體之檢體，作為診斷疾病、決定健康狀態或其他狀況，而使用之試劑、儀器、軟體或系統。

四、類似品：指具有下列條件之一，於國內已取得許可證或登錄之醫療器材：

（一）與擬申請許可證或登錄之醫療器材，具有同等預期用途及技術特點。

（二）與擬申請許可證或登錄之前款以外醫療器材，具有同等預期用途，不同技術特點，而不影響產品安全及效能。

第二章　醫療器材查驗登記及許可證核發

第3條

申請醫療器材製造、輸入查驗登記發給許可證者，應依第五條及第六條規定檢具文件、資料，並繳納費用，向中央主管機關提出。

經中央主管機關公告之品項，申請前項查驗登記，應依中央主管機關之送驗通知，於規定期限內繳納檢驗費，並檢具足供檢驗所需之樣品，辦理送驗手續。但專供外銷者，不在此限。

第一項許可證，登記事項如下：

一、中英文品名。

二、醫療器材商名稱。

三、醫療器材製造業者名稱及地址。

四、效能、用途或適應症。

五、醫療器材成分、材料、結構、規格或型號。

75

[Regulations for the Issuance, Registration, and Annual Declaration of Medical Device Licenses] (Amended on 2023.11.27)

Chapter 1 General Provisions

Article 1

These Regulations are formulated pursuant to Article 29 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

The terms used in these Regulations are defined as follows:

1. Certificate of Free Sale from the Country of Origin: refers to documentary evidence issued by the highest health authority or institution of the manufacturing country of the imported medical device, certifying that the said medical device is permitted to be manufactured and freely sold in that country.

2. Letter of Authorization for Registration from the Overseas Original Manufacturer: refers to the documentary evidence issued by the original overseas manufacturer of the imported medical device, authorizing an agent.

3. In Vitro Diagnostic Device (IVD): refers to reagents, instruments, software, or systems used to collect, process, or examine specimens taken from the human body for the purpose of diagnosing diseases, determining health status, or other conditions.

4. Similar Products: refers to medical devices that satisfy any of the following conditions and have already obtained a license or registration domestically:

(1) Medical devices proposed for license or registration that have the same intended use and technical characteristics.

(2) Apart from the preceding subparagraph, medical devices proposed for license or registration that have the same intended use but different technical characteristics, provided that product safety and efficacy are not affected.

Chapter 2 Medical Device Verification Registration and License Issuance

Article 3

Applicants for manufacturing or importing medical devices and seeking verification registration and issuance of license shall submit the documents and information as specified in Articles 5 and 6, pay the required fees, and apply to the central competent authority.

For items publicly announced by the central competent authority, applicants for the aforesaid verification registration shall, in accordance with the notification from the central competent authority, pay the inspection fee within the specified period and submit sufficient samples required for inspection to complete the submission procedure. However, this does not apply to products exclusively for export.

The particulars to be registered for the license in Paragraph 1 are as follows:

1. Product name in both Chinese and English.

2. Name of the medical device firm.

3. Name and address of the medical device manufacturer.

4. Performance, intended use, or indications.

5. Composition, materials, structure, specifications, or model of the medical device.

Translated by RegDesk AI

六、標籤、說明書或包裝。

七、製造許可編號。

八、其他經中央主管機關指定登記事項。

第4條

前條醫療器材品名，應符合下列規定：

一、不得使用他人醫療器材商標或廠商名稱。但該產品已取得商標或經授權使用者，不在此限。

二、不得與其他廠商醫療器材品名相同或近似，致與其他廠商醫療器材發生混淆。

三、不得有虛偽、誇大，或使人對醫療器材用途、效能產生不當聯想或混淆。

四、中文品名不得夾雜外文或數字。但經中央主管機關認定具直接意義或英文商標具特殊意義者，不在此限。

五、專供外銷醫療器材之中英文品名，不得與國內銷售醫療器材之中英文品名相同。

醫療器材品名相同或近似之認定，應依商標、廠商名稱或其他可資辨別名稱之順位判斷之。

第5條

申請製造、輸入第一等級醫療器材查驗登記，其應檢具之文件、資料，規定如附表一。

前項申請，中央主管機關得免核定第三條第三項第五款、第六款登記事項。

第6條

申請製造、輸入第二等級或第三等級醫療器材之查驗登記，其應檢具之文件、資料，除第十九條第二項規定外，如附表二及附表三。

前項申請，其產品屬專供外銷者，中央主管機關得免核定第三條第三項第五款、第六款登記事項。

第7條

中央主管機關受理查驗登記申請案後，應就申請文件、資料進行形式審查。

前項形式審查，發現申請文件、資料有不備，其得補正者，中央主管機關應通知申請人於一個月內補正；屆期未補正者，予以駁回。

6. Label, instructions for use, or packaging.

7. Manufacturing license number.

8. Other items designated for registration by the central competent authority.

Article 4

The product name of the medical device in the preceding Article shall comply with the following provisions:

1. The trademark or manufacturer’s name of another medical device shall not be used. However, this restriction does not apply if the product has obtained the trademark or is authorized for use.

2. The product name shall not be identical or similar to that of another manufacturer’s medical device, so as to avoid confusion with other manufacturers’ medical devices.

3. It shall not be false, exaggerated, or likely to cause inappropriate associations or confusion regarding the purpose or efficacy of the medical device.

4. Chinese product names shall not contain foreign languages or numbers. However, this restriction does not apply where the central competent authority determines that the term has a direct meaning, or the English trademark has a specific significance.

5. The Chinese and English product names for medical devices exclusively for export shall not be identical to those for domestically marketed medical devices.

The determination of whether a medical device product name is identical or similar shall be made based on the order of trademark, manufacturer’s name, or other distinguishable names.

Article 5

To apply for the registration and inspection of manufacturing or importing Class I medical devices, the required documents and information shall be as specified in Annex 1.

For the application in the preceding paragraph, the central competent authority may exempt the registration items specified in Article 3, Paragraph 3, Subparagraphs 5 and 6.

Article 6

To apply for the registration and inspection of manufacturing or importing Class II or Class III medical devices, the required documents and information, except as otherwise provided in Article 19, Paragraph 2, shall be as specified in Annex 2 and Annex 3.

For the application in the preceding paragraph, if the product is exclusively for export, the central competent authority may exempt the registration items specified in Article 3, Paragraph 3, Subparagraphs 5 and 6.

Article 7

Upon accepting an application for registration and inspection, the central competent authority shall conduct a formal review of the application documents and information.

If deficiencies are found in the documents or information during the formal review and such deficiencies can be rectified, the central competent authority shall notify the applicant to make corrections within one month; if corrections are not made within the deadline, the application shall be rejected.

Translated by RegDesk AI

第8條

申請案經完成前條形式審查後，中央主管機關應進行實質審查。

前項實質審查發現文件、資料有不完足，其得補正者，中央主管機關應通知申請人於三個月內補正；屆期未補正者，予以駁回。

第9條

申請案有下列情形之一者，申請人得檢具佐證之文件、資料，向中央主管機關提出優先審查：

一、用於預防、診斷或治療危及生命或嚴重失能之疾病，且國內尚無適當藥品、醫療器材或合適替代療法。

二、用於預防、診斷或治療罕見疾病防治及藥物法第三條第一項所定之罕見疾病。

三、經中央主管機關或其他機關依政策優先輔導、補助研發，且已於或將於國內進行臨床試驗驗證其安全及效能，或具國內公共衛生或醫療迫切需求。

第10條

申請案經實質審查後，有下列情形之一者，不予核准：

一、繳納費用不符規定。

二、檢具之文件、資料不完備或與申請案內容不符。

三、未依規定辦理送驗手續，或送驗之樣品經檢驗不合格。

四、申請之醫療器材，其危害人體健康之風險大於利益。

五、其他與法令規定不符之情事。

第11條

申請案之審查結果，中央主管機關應通知申請人；經核准發給許可證者，申請人應自通知送達之日起三個月內，繳納證書費用，並依核定內容製作標籤、說明書或包裝，向中央主管機關請領許可證。

申請人未依前項規定完成領證者，中央主管機關得廢止其許可證。

第12條

申請案經中央主管機關初步認定其具備申請效能，無重大風險，且有下列情形之一者，中央主管機關得要求申請人提供安全監視或上市後研究之計畫書，經審查後，得發給較短效期之許可證：

一、用於預防、診斷或治療危及生命或嚴重失能之疾病，且國內尚無適當藥品、醫療器材或合適替代療法。

二、具國內公共衛生或醫療急迫需求。

Article 8

After completion of the formal examination as prescribed in the preceding article, the central competent authority shall conduct a substantive examination.

If during the substantive examination in the preceding paragraph, any document or data is found to be incomplete but can be rectified, the central competent authority shall notify the applicant to make the correction within three months; the application will be rejected if the correction is not made within the specified period.

Article 9

For applications falling under any of the following circumstances, the applicant may submit supporting documents and materials to the central competent authority to request priority examination:

1. For the prevention, diagnosis, or treatment of life-threatening diseases or diseases causing severe disability, where there is no appropriate drug, medical device, or suitable alternative therapy available domestically.

2. For the prevention, diagnosis, or treatment of rare diseases as defined in Article 3, Paragraph 1 of the Rare Disease Prevention and Orphan Drug Act.

3. Where research and development has been prioritized and subsidized by the central competent authority or other authorities as a matter of policy, and clinical trial(s) have been, or will be, conducted domestically to verify safety and efficacy, or where there is an urgent domestic public health or medical need.

Article 10

After substantive examination, the application shall not be approved under any of the following circumstances:

1. Nonpayment or insufficient payment of the required fees.

2. The submitted documents or materials are incomplete or inconsistent with the content of the application.

3. Failure to follow mandated procedures for sample submission or submitted samples fail inspection.

4. The harm to human health from the medical device applied for exceeds its benefits.

5. Other circumstances that do not comply with legal and regulatory provisions.

Article 11

The central competent authority shall notify the applicant of the review result of the application; for those approved and granted a permit, the applicant shall, within three months from the date of receiving the notification, pay the certificate issuance fee, prepare labels, instructions, or packaging in accordance with the approved content, and apply to the central competent authority for the permit.

If the applicant fails to complete permit collection pursuant to the preceding paragraph, the central competent authority may revoke the permit.

Article 12

For an application that the central competent authority preliminarily determines to possess functional efficacy, is free from major risks, and falls under any of the following circumstances, the central competent authority may require the applicant to provide a safety monitoring or post-market research plan, and upon review, may grant a permit with a shorter validity period:

Translated by RegDesk AI

1. For the prevention, diagnosis, or treatment of life-threatening diseases or diseases causing severe disability, where there is no appropriate drug, medical device, or suitable alternative therapy available domestically.

2. Meets urgent domestic public health or medical needs.

Translated by RegDesk AI

三、具創新性或新穎性，且有顯著臨床效益，得用於提升或輔助醫療診斷與治療。

申請人未依前項計畫書進行安全監視或上市後研究者，中央主管機關得廢止其許可證。

第三章　許可證之變更、補發或換發

第13條

許可證之登記事項、標籤、說明書或包裝有下列各款事項之一變更者，應檢具附表四之文件、資料，並繳納費用，向中央主管機關提出申請：

一、中文品名。

二、英文品名。

三、原廠標籤、說明書或包裝。

四、成分、材料、結構、規格或型號。

五、效能、用途或適應症。

六、製造業者名稱。

七、製造業者地址或製造國別。

八、許可證所有人。

九、許可證所有人名稱。

十、製造許可編號。

許可證或標籤、說明書或包裝之核定文件有遺失或污損時，應檢具附表四之文件、資料，並繳納費用，申請補發或換發。

中央主管機關審查發現前二項文件、資料有不備，其得補正者，應通知申請人於三個月內補正；屆期未補正者，予以駁回。

第二項補發或換發許可證之申請，申請人應自通知送達之日起三個月內，繳納證書費用，向中央主管機關請領許可證。屆期未完成領證者，中央主管機關得廢止其許可證。

第一項、第二項申請，中央主管機關應於原許可證加註變更登記事項、日期及加蓋章戳後發還之。

第13-1條

經中央主管機關公告之品項，申請前條第一項第四款或第七款之變更，準用第三條第二項之規定辦理。

第14條

醫療器材之標籤、說明書或包裝變更時，有下列情形之一者，許可證所有人得自行變更，並製作變更紀錄：

78

3. Products that possess innovation or novelty and demonstrate significant clinical benefits may be used to enhance or assist medical diagnosis and treatment.

If the applicant fails to conduct safety surveillance or post-market studies in accordance with the plan described in the preceding paragraph, the central competent authority may revoke its license.

Chapter 3 Change, Reissuance, or Replacement of Licenses

Article 13

If there is any change in the registration items, labeling, instructions, or packaging of a license involving any of the following items, the applicant shall submit the documents and information specified in Appendix 4 and pay the required fees to apply to the central competent authority:

1. Chinese product name.

2. English product name.

3. Original manufacturer’s labeling, instructions, or packaging.

4. Ingredients, materials, structure, specifications, or model.

5. Efficacy, purpose, or indications.

6. Name of the manufacturer.

7. Manufacturer’s address or country of manufacture.

8. License holder.

9. Name of the license holder.

10. Manufacturing permit number.

If the approved license or the approved labeling, instructions, or packaging documents are lost or damaged, the applicant shall submit the documents and information specified in Appendix 4, pay the required fees, and apply for reissuance or replacement.

If, upon review, the central competent authority finds that the documents or information submitted under the preceding two paragraphs are incomplete but amendable, it shall notify the applicant to make corrections within three months. Failure to make corrections within the deadline will result in rejection of the application.

For applications for reissuance or replacement of a license under paragraph two, the applicant shall, within three months from the date of receipt of the notification, pay the certificate fee and claim the license from the central competent authority. If the applicant fails to claim the license within the deadline, the central competent authority may revoke the license.

For applications under paragraphs one and two, the central competent authority shall add annotations of the changed registration items, date, and affix the official stamp on the original license before returning it.

Article 13-1

For items publicly announced by the central competent authority, changes under subparagraph 4 or 7 of paragraph one of the preceding article shall be handled in accordance with the provisions of Article 3, paragraph 2.

Article 14

Translated by RegDesk AI

When changes are made to the labeling, instructions, or packaging of medical devices, if any of the following circumstances apply, the license holder may make the change independently and create a change record:

Translated by RegDesk AI

一、文字內容未變更：

（一）僅標籤、說明書、外盒之材質、形狀、圖樣或色澤變更，且無猥褻、傷風化或誤導效能之圖樣。

（二）因包裝數量不同，而依比例縮小或放大原核准之圖文，或更改原核准圖文位置之版面移動。

（三）原核准文字之字體更改，且其品名英文字體未大於中文字體。

（四）由標籤黏貼改為外盒印刷或增加外盒者，且其文字、圖樣之設計與原核准標籤相同。

二、屬下列文字內容變更：

（一）增印或變更條碼、回收標誌、醫療器材業者之QMS／GMP字樣、CE標誌、建議售價、消費者服務專線、電話、傳真、聯絡處、經濟部智慧財產局核准註冊之公司商標、CNS或註冊商標字號、其他國家或地區代表資訊。

（二）增印或變更經銷商名稱、地址，且經銷商名稱字體未大於醫療器材商（許可證所有人）名稱字體。

（三）增印或變更經中央主管機關核准變更之醫療器材商名稱、製造業者名稱或地址。

（四）增、刪或變更經中央主管機關核准變更之中、英文品名加註之醫療器材商名稱。

（五）增、刪或變更可表徵許可證核准登記事項之國際標示符號。

三、依本法第三十三條第一項第十款公告增印、刪除或變更之刊載事項。

第15條

申請變更第一等級醫療器材者，其檢具之文件、資料，準用第五條規定。

第16條

申請變更專供外銷醫療器材者，其檢具之文件、資料，準用第六條規定。

第四章　許可證之展延

第17條

申請許可證有效期限展延者，應於期限屆至前六個月內，填具申請書，並檢具下列文件、資料，及繳納費用，向中央主管機關提出：

一、原許可證。

二、出產國許可製售證明；國內製造者，免附。

三、國外原廠授權登記書；國內製造者，免附。

四、製造業者符合醫療器材品質管理系統準則之證明文件。

79

I. No Change in Text Content:

(1) Only the material, shape, pattern, or color of the label, instructions, or outer packaging has changed, and the pattern does not contain obscenity, is not contrary to public morals, nor misleading regarding efficacy.

(2) Due to different packaging quantities, the originally approved text and images are proportionally enlarged or reduced, or the layout position of the original approved text and images is changed.

(3) The font of the original approved text is changed, and the English brand name font is not larger than the Chinese font.

(4) Changing from adhesive labels to printed outer box or adding an outer box, where the design of the text and pattern is identical to the originally approved label.

II. The following text content changes are included:

(1) Addition or change of barcodes, recycling marks, QMS/GMP marks for medical device operators, CE mark, suggested retail price, consumer service hotline, telephone, fax, contact address, company trademark approved and registered by the Intellectual Property Office of the Ministry of Economic Affairs, CNS or registered trademark numbers, or other country or regional representative information.

(2) Addition or change of the distributor’s name or address, and the font of the distributor’s name is not larger than that of the medical device operator (permit holder).

(3) Addition or change of the name or address of the medical device operator or manufacturer, as approved for change by the central competent authority.

(4) Addition, deletion, or change of the Chinese or English brand names of the medical device operator annotated, as approved for change by the central competent authority.

(5) Addition, deletion, or change of international symbols representing items registered on the permit as approved.

III. According to the public announcement under Article 33, Paragraph 1, Subparagraph 10 of this Act, addition, deletion, or change of published items.

Article 15

For applications to change Class I medical devices, the documents and information required shall apply mutatis mutandis to the provisions of Article 5.

Article 16

For applications to change medical devices intended exclusively for export, the documents and information required shall apply mutatis mutandis to the provisions of Article 6.

Chapter 4 Extension of Permit Validity Period

Article 17

For applications for extension of the validity period of a permit, the application form shall be completed and submitted with the following documents, information, and payment of the prescribed fee to the central competent authority within six months prior to the expiration date:

1. The original permit.

2. Proof of approval for manufacture and sale from the country of origin; domestic manufacturers are exempt.

Translated by RegDesk AI

3. Authorization letter of registration from the original foreign manufacturer; domestic manufacturers are exempt.

4. Proof documents showing that the manufacturer complies with the Medical Device Quality Management System Standards.

Translated by RegDesk AI

五、依第十二條第一項規定核發之許可證，應檢具安全監視或上市後研究計畫報告。

六、其他經中央主管機關指定之文件、資料。

中央主管機關審查發現前項文件、資料有不備，其得補正者，應通知申請人於三個月內補正；屆期未補正者，予以駁回。

第18條

申請展延第一等級醫療器材許可證者，其檢具之文件、資料，準用第五條規定。

第19條

許可證有效期限屆至前，未依第十七條規定申請展延者，應依第五條及第六條規定，重新申請查驗登記發給許可證。

前項申請屬第二等級、第三等級醫療器材許可證，且於有效期限屆至後六個月內重新申請者，其應檢具之文件、資料如下，不受第六條規定之限制：

一、醫療器材商許可執照。

二、原許可證。

三、原核准並蓋有中央主管機關核定章之標籤、說明書或包裝。

四、標籤、說明書或包裝擬稿。

五、出產國許可製售證明；國內製造者，免附。

六、國外原廠授權登記書；國內製造者，免附。

七、製造業者符合醫療器材品質管理系統準則之證明文件。

八、其他經中央主管機關指定之文件、資料。

第一項申請案經核准後，以新字號發給許可證

第五章　登錄及年度申報

第20條

申請製造或輸入醫療器材登錄者，應於中央主管機關建置之醫療器材登錄系統（以下簡稱登錄系統）登錄下列事項，並依附表五之規定上傳備查文件、資料，及繳納費用，取得登錄字號：

一、中英文品名。

二、醫療器材商名稱。

三、製造業者名稱及地址。

四、醫療器材分類品項名稱及代碼。

五、醫療器材之滅菌狀態。

5. For a permit issued in accordance with Article 12, Paragraph 1, a safety surveillance or post-market study report shall be submitted.

6. Other documents and materials designated by the central competent authority.

If, upon review, the central competent authority finds the documents and materials specified in the preceding paragraph to be incomplete, and if supplementation is permissible, the applicant shall be notified to make corrections within three months. Failure to make corrections within the specified period shall result in rejection of the application.

Article 18

For applications to extend the permit for first-class medical devices, the documents and materials to be submitted shall be handled in accordance with the provisions of Article 5.

Article 19

If, prior to the expiration of the permit, an application for extension is not submitted in accordance with Article 17, a new application for examination and registration for permit issuance shall be filed in accordance with the provisions of Articles 5 and 6.

For applications in the preceding paragraph involving permits for second-class or third-class medical devices, if a new application is filed within six months after expiration, the following documents and materials shall be submitted, and the restrictions of Article 6 shall not apply:

1. Medical device dealer permit.

2. Original permit.

3. Original approved labels, instructions for use, or packaging bearing the central competent authority’s approval seal.

4. Drafts of labels, instructions for use, or packaging.

5. Certificate of manufacturing and marketing approval from the country of origin; not required for domestic manufacturers.

6. Letter of authorization for registration from the original overseas manufacturer; not required for domestic manufacturers.

7. Documentation proving that the manufacturer complies with Good Manufacturing Practice (GMP) requirements for medical devices.

8. Other documents and materials designated by the central competent authority.

Once the application under Paragraph 1 is approved, a new permit number shall be issued.

Chapter 5 Registration and Annual Declaration

Article 20

Applicants seeking to register the manufacturing or importation of medical devices shall enter the following items into the medical device registration system established by the central competent authority (hereinafter referred to as the "registration system"), upload supporting documents and materials in accordance with the requirements set out in Appendix 5, and pay the applicable fees to obtain a registration number:

1. Product name in both Chinese and English.

2. Name of the medical device dealer.

3. Name and address of the manufacturer.

Translated by RegDesk AI

4. Name and code of the medical device classification and category.

5. Sterilization status of the medical device.

Translated by RegDesk AI

六、製造業者符合醫療器材品質管理系統準則之情形。

七、其他經中央主管機關指定之文件、資料。

前項醫療器材之品名，準用第四條規定。

第21條

前條第一項第四款以外各款登錄事項變更者，應於登錄系統申請變更，並繳納費用。

前項申請變更，申請者應準用前條之規定，上傳備查文件、資料。

前條第一項第二款醫療器材商名稱之變更，以未涉及權利移轉者為限。

前條第一項第四款醫療器材分類品項名稱及代碼，不得申請登錄變更。

第22條

完成登錄滿一年者，應每年十月於登錄系統辦理年度申報，確認下列事項之登錄情形，並繳納費用：

一、中英文品名。

二、醫療器材商名稱。

三、製造業者名稱及地址。

四、醫療器材分類品項名稱及代碼。

五、製造業者符合醫療器材品質管理系統準則之情形。

六、醫療器材之滅菌狀態。

七、其他經中央主管機關指定之文件、資料。

第23條

中央主管機關依本法第二十五條第四項規定逕予登錄者，醫療器材商應於原許可證有效期限屆至後，依前條規定申報。

第六章　附則

第24條

依本準則辦理之申請案，申請人檢具之文件、資料，非正體中文或英文者，應檢附正體中文或英文譯本。

第25條

申請案涉及委託製造者，申請人應檢具依醫療器材委託製造作業準則規定取得之核准證明文件。

第26條

本準則自中華民國一百十年五月一日施行。

本準則修正條文，自發布日施行。

81

6. Circumstances in which the manufacturer complies with the Medical Device Quality Management System Requirements.

7. Other documents and materials as designated by the central competent authority.

The product name of the medical device mentioned in the preceding paragraph shall apply mutatis mutandis to the provisions of Article 4.

Article 21

For changes to registration particulars other than those specified in Subparagraph 4, Paragraph 1 of the preceding article, an application for change shall be submitted through the registration system, and fees shall be paid.

For the foregoing application for change, the applicant shall apply mutatis mutandis to the provisions of the preceding article and upload the required documents and materials for reference.

Changes to the name of the medical device firm under Subparagraph 2, Paragraph 1 of the preceding article are limited to cases not involving the transfer of rights.

Applications for change of the name and code of the classification item of the medical device under Subparagraph 4, Paragraph 1 of the preceding article shall not be accepted for registration change.

Article 22

For registrations that have been completed for one full year, an annual declaration shall be submitted in the registration system every October to verify the registration status of the following items, and fees shall be paid:

1. Name of the product in Chinese and English.

2. Name of the medical device firm.

3. Name and address of the manufacturer.

4. Name and code of the classification item of the medical device.

5. Circumstances in which the manufacturer complies with the Medical Device Quality Management System Requirements.

6. Sterilization status of the medical device.

7. Other documents and materials as designated by the central competent authority.

Article 23

For cases where the central competent authority directly registers in accordance with Paragraph 4, Article 25 of the Act, the medical device firm shall, after the original permit expires, declare pursuant to the preceding article.

Chapter VI Supplementary Provisions

Article 24

For applications handled in accordance with these Regulations, where documents and materials submitted by the applicant are not in Traditional Chinese or English, a Traditional Chinese or English translation shall be attached.

Article 25

For applications involving contract manufacturing, the applicant shall submit proof of approval obtained pursuant to the Regulations for Contract Manufacturing Operations of Medical Devices.

Translated by RegDesk AI

Article 26

These Regulations shall enter into force on May 1, 2021.

The amended provisions of these Regulations shall take effect from the date of promulgation.

Translated by RegDesk AI

附表一 申請製造、輸入第一等級醫療器材查驗登記應檢具之文件、資料

項目	申請類別	製造	輸入
1	第一等級醫療器材查驗登記申請書	○	○
2	醫療器材商許可執照影本	○	○
3	醫療器材製造業者符合醫療器材品質管理系統準則之證明文件	△	△
4	原廠產品說明書資料	△	△
5	臨床前測試之檢驗規格與方法及檢驗成績書	△	△
6	其他經中央主管機關指定之文件、資料	△	△

說明：

一、○：表示須檢附該項目之資料。△：表示視個案而定。

二、醫療器材商許可執照影本：

（一）製造醫療器材者，應檢附醫療器材製造業許可執照影本。輸入醫療器材者，應檢附營業項目包含“輸入”之醫療器材販賣業許可執照影本。

（二）國內委託製造者，應檢附委託者及受託製造業者之醫療器材商許可執照。

三、醫療器材製造業者符合醫療器材品質管理系統準則之證明文件：本項文件指由中央主管機關核發之醫療器材製造業者符合醫療器材品質管理系統準則之證明文件影本。但經中央主管機關公告免取得製造許可之品項，免附。

四、原廠產品說明書資料：應包含醫療器材之使用方法、功能、工作原理、產品組成(或成分)之說明，且其內容足以供認定該醫療產品符合第一等級品項鑑別之資料。

ENGLISH TRANSLATION · Orig. Pg 85

Appendix 1 - Documents and Materials Required for Applying for Manufacture or Import of Class I Medical Devices

I...	Application Type	Manufa..	Im...
1	Application for Registration and Inspection of Class I Medical Devices	○	○
2	Photocopy of Medical Device License	○	○
3	Documents verifying compliance with medical device quality management system standards by the manufacturer	△	△
4	Original product description and information	○	○
5	Report on clinical pre-test inspection criteria and inspection results	△	△
6	Other documents designated by the central competent authority	△	△

Explanation:

1. ○: Required documents for the respective item. △: Case-by-case determination.

2. Photocopy of Medical Device License:

- (1) For imported medical devices, photocopies of documents proving the manufacturer complies with medical device quality management system standards or included with the application. If the item includes "import" medical device dealer business license, a photocopy is required.

- (2) For domestically commissioned manufacturers, a photocopy of the medical device dealer's business license approved by the commissioning entity and accepted by the manufacturer is required.

3. Documents Verifying Compliance with Medical Device Quality Management System Standards:

- This item refers to documents verified by the central competent authority confirming the manufacturer's compliance with medical device quality management system standards. A photocopy of the document should be attached. However, if the central competent authority announces an exemption for manufacturing licensing for both items, this may be waived.

4. Original Product Description and Information: Should include the method of use, functions, working principles, composition (or ingredients) and explanatory information of the medical device. The content must be sufficient to certify that the device complies with Class I product standards.

Translated by RegDesk AI

五、臨床前測試之檢驗規格與方法及檢驗成績書：第一等級醫療器材品項鑑別或經中央主管機關依本法第三十條公告，對於產品性能規格有規定者，應檢附本項文件。

六、其他經中央主管機關指定之文件、資料：

（一）品名冠有商標者，應檢附商標註冊相關資料。品名冠有其他廠商之名稱或商標者，應檢附被加冠者出具之同意函。

（二）為配合經濟部國際貿易局公告之限制輸入貨品及海關協助查核輸入貨品彙總表，輸入產地為中國之醫療器材，應先向經濟部國際貿易局取得准許輸入之證明文件，始得向中央主管機關申請查驗登記。

（三）品名冠有特定國家或國際組織標準之性能規格專有名詞者，應檢附該地區國家、第三方驗證單位或國際組織出具之佐證文件。

V. Preclinical testing, inspection methods, results, and performance: For Class I medical devices or diagnostic agents, according to the announcements by the central competent authority under Article 30 of this law; documents must be attached for products with performance specifications.

VI. Other documents designated by the central competent authority: Requirements:

(1) For products registered with trademarks, the trademark registration certificate and related information should be attached. If the product has another factory's name or trademark, a document stating the factory location and country of origin should be attached.

(2) To comply with the restrictions on the import of goods announced by the Ministry of Economic Affairs' International Trade Bureau and assist in checking import goods, a complete list of the imported goods should be compiled. For products made in China, they should first obtain approval and import permit documents from the International Trade Bureau of the Ministry of Economic Affairs before submitting inspection registration to the central competent authority.

(3) If the product is certified by a designated country's or an international organization's standard and has performance specifications verified by a professional, documentation from the certifying country, a third-party certifying agency, or an international organization should be attached as verification.

Translated by RegDesk AI

附表二 申請製造、輸入第二等級或第三等級醫療器材查驗登記應檢具之文件、資料

申請類別 / 應檢附文件、資料項目		第二等級醫療器材		第三等級醫療器材		同一產品不同品名		專供外銷
		製造	輸入	製造	輸入	製造	輸入	製造
1	醫療器材查驗登記申請書	○	○	○	○	○	○	○
2	標籤、說明書或包裝擬稿二份	○	○	○	○	○	○	×
3	醫療器材商許可執照影本	○	○	○	○	○	○	○
4	出產國許可製售證明正本	×	△	×	△	×	○	×
5	國外原廠授權登記書正本	×	○	×	○	×	○	×
6	醫療器材製造業者符合醫療器材品質管理系統準則之證明文件	○	○	○	○	×	×	○
7	臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書	△	△	○	○	×	×	×
8	產品之結構、材料、規格、性能、用途、圖樣等有關資料	○	○	○	○	×	×	×
9	臨床證據資料	△	△	△	△	×	×	×
10	發生游離輻射器材之輻射防護安全資料	△	△	△	△	×	×	×
11	醫療器材安全性與功效性基本規範及技術文件摘要	×	△	○	○	×	×	×

Appendix 2 Required Documents and Information for Application for Manufacture or Import of Class II or Class III Medical Devices for Registration Inspection

Application Type	Class II Medical Devices	Class III Medical Devices	Identical Products Not Name	Compo Suppl..			
	Manufa...	Import	Manufact...	Import	M...	I...	M...
Required Attachments / Information							
1. Medical Device Basic Registration Application Form	○	○	○	○	○	○	○
2. Images, Specifications, or Colored Photocopied Sheets of Labels	○	○	○	○	○	○	○
3. Photos of the Medical Device Main Body	○	○	○	○	○	○	○
4. Copy of Export Country Manufacturer's License	△	○	X	○	△	○	X
5. Foreign Manufacturer's Business Registration Certificate	○	○	○	○	X	○	X
6. Document on Compliance of Medical Device Manufacturers or Quality Management System Standard(s)	○	○	○	○	X	X	X
7. Testing Data and Original Inspection Records of Raw Material and Quality Management Procedure of Medical Device Release or Corresponding Documentation	○	△	△	○	△	○	X
8. Information Related to the Product's Composition, Material, Specifications, Performance, Use, and Model	○	○	△	○	X	○	X
9. Clinical Data	△	△	X	△	X	△	X
10. Radiation Protection Safety Data for Devices Emitting Non-ionizing Radiation	△	△	X	△	X	X	X
11. Essential Safety and Performance Technical Documentation Summary of Medical Devices	X	○	○	○	○	X	X

Legend:

○ = Required

△ = Optional

X = Not Required

Page 84

Translated by RegDesk AI

12	原廠同一產品不同品名之說明函正本	╳	╳	╳	╳	○	○	╳
13	原核准並蓋有中央主管機關核定章之標籤、說明書或包裝影本一份	╳	╳	╳	╳	○	○	╳
14	原核准之醫療器材許可證影本	╳	╳	╳	╳	○	○	╳
15	其他經中央主管機關指定之文件、資料	△	△	△	△	△	△	△
16	送驗	△	△	△	△	╳	╳	╳

說明：

一、○：表示須檢附該項目之資料。△：表示視個案而定。╳：表示不須檢附該項目之資料。

二、標籤、說明書或包裝擬稿：

(一)製造醫療器材者，中文標籤、說明書或包裝，及產品實際外觀彩色圖片擬稿。

(二)輸入醫療器材者，原廠標籤、說明書或包裝，與其詳細中文說明書擬稿及產品實際外觀彩色圖片擬稿。

三、醫療器材商許可執照影本：

(一)製造醫療器材者，應檢附醫療器材製造業許可執照影本。輸入醫療器材者，應檢附營業項目包含“輸入”之醫療器材販賣業許可執照影本。

(二)國內委託製造者，應檢附委託者及受託製造業者之醫療器材商許可執照。

四、出產國許可製售證明：

(一)本項文件應記載下列事項：

1、醫療器材之名稱、規格型號。

2、製造業者名稱、地址、製造情形及核准在其本國販賣實況。

(二)本項文件得依下列規定，由其他單位出具或以其他文件替代

12 | Certificates or same product with different names explained properly.

13 | Certificates or approval from the central governing authority.

14 | Photos of the product’s design or structure, explanatory document or colored photos.

15 | Certificates or labels for approved medical materials.

16 | Other files or documents specified by the central governing authority.

Explanation:

○: Must include relevant documents for the item.

△: To be determined case by case.

×: No need to include relevant documents for the item.

1. Description, explanatory documents or packaging:

(1) Manufactured medical materials: Must include Chinese description, explanatory documents, packaging, and external view colored photos.

(2) Imported medical materials: Must include original description, explanatory documents, packaging, along with detailed Chinese documentation and imported product external view colored photos.

2. Medical materials must provide photos:

(1) Manufactured medical materials: Should attach the medical material's manufacturing business approval photo. Imported medical materials: Approval items containing "import" in medical material fee notice must attach photos.

(2) Domestic packaging manufacturers: Should attach fiscal authority entrusted with the medical materials production business approval photo.

3. Additional documents or photos should include:

1. Name of medical material or standard model number.

2. Manufacturer’s name, address, manufacturer’s registration and approval status.

(See additional regulations for substitute documents issued by other units.)

Translated by RegDesk AI

之：

1、產製國最高衛生單位未列管者，得由當地衛生機關或我國中央主管機關認可之機構出具。

2、委託製造者，得由委託者或受託製造業者其中之一所在國家之最高衛生單位出具。

3、委託製造且未於受託製造業者所在國家上市者，得以委託者所在國家之最高衛生單位出具之自由販賣證明，及受託製造業者所在國家官方出具之製造證明替代之。

4、得以產製國官方出具之製造證明，及美國或歐盟會員國最高衛生單位出具之自由販賣證明替代之。

5、全球首創無類似品者，檢附經中央主管機關進行國外醫療器材製造業者實地查核之報告及在我國進行醫療器材臨床試驗之報告，免附出產國許可製售證明。

（三）本項文件限出具日起二年內有效，且應經我國駐該地區之駐外使領館、代表處、辦事處或外交部授權之駐外機構（以下簡稱我國駐外館處）驗證。其證明文件如非以英文出具者，應同時檢附中文或英文譯本，且譯本應經驗證。但與我國訂有醫療器材上市前審查技術合作協議國家之最高衛生單位出具者或經中央主管機關認定者，得免驗證。

五、國外原廠授權登記書：

（一）本項文件應記載下列事項：

1、原製造業者授權我國代理商申請查驗登記，並配合我國代理商符合醫療器材相關管理規定。

2、指明其委託或授權登記之醫療器材商名稱、地址與醫療器材之名稱、規格型號等。

（二）本項文件得依下列規定，以其他文件替代之：

1、輸入醫療器材總公司出具之授權代理證明文件，授權我國代理商申請查驗登記，其內容載明製造業者名稱、地址，並指明其委託或授權登記之醫療器材商名稱、地址與醫療器材之名稱、規格型號等。

Notes:

1. If the manufacturer of the highest sanitary unit does not list, the organization can be authorized by the central competent authority of our country for certification.

2. If the manufacturer authorizes, the authorized manufacturer among them can issue the manufacturer certificate of the highest sanitary unit in our country.

3. If the manufacturer establishes a factory in the country that the manufacturer is not in, it can issue its manufacturer certificate of the highest sanitary unit in our country and apply for the certificate at the official mission or representative office in our country.

4. If the official mission of the manufacturer only certifies or certifies the local official mission in my country, and the colleagues of our highest sanitary unit can replace it with free purchase certification in my country.

5. If temporarily unable to provide licenses issued by foreign medical devices, they may be exempted according to the review results of our country's central competent health and welfare administration, provided that they attach the corporate registry certificate and other relevant documents when exporting to our country.

(2) This document is effective for three years from the date of its promulgation and continuously effective at overseas missions and representative offices in this country (hereinafter referred to as overseas troops); upon expiration, application for extension must be made according to the review results. Once determined that the registration validity of the medical device has expired, the original approval is void, but for material registration of such expired devices, after negotiation for cooperation with manufacturers, the highest sanitary unit in our country can be approved with the decision of the central authority.

5. Note the following regarding foreign original authorization:

(1) This document should state the following matters:

1. The manufacturer's authorized agent should be registered with our country and should comply with our country's relevant management regulations for medical devices.

2. It should clearly state the authorized or registered medical device manufacturer's name, address, and product name, model number.

(2) This document should be attached with other documents as specified:

1. The foreign medical device manufacturer's company should issue the original authorization document, which states the manufacturer's name, address, and the names, model numbers, etc., of the authorized or registered medical devices.

Translated by RegDesk AI

2、由輸入醫療器材原製造業者出具說明其國外代理商之證明文件，再由國外代理商出具之授權代理證明文件，授權我國代理商申請查驗登記，並指明其委託或授權登記之醫療器材商名稱、地址與醫療器材之名稱、規格型號等。

(三)本項文件限出具日起一年內有效；如非以英文出具者，並應同時檢附中文或英文譯本。

六、醫療器材製造業者符合醫療器材品質管理系統準則之證明文件：

(一)本項文件指由中央主管機關核發之醫療器材製造業者符合醫療器材品質管理系統準則之證明文件影本。

(二)原列屬藥品管理者，於公告改列醫療器材之日起三年內，得以符合藥品優良製造規範之證明文件影本替代之。

七、臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書：

(一)本項文件包括為確保產品宣稱效能、結構、材質、設計及品質所進行之安全性及功能性檢測等資料。

(二)已有類似品經中央主管機關核准上市之第二等級醫療器材者，得以下列文件之一替代之：

1、與我國訂有醫療器材上市前審查技術合作協議國家官方所出具之核准上市證明文件，以及醫療器材安全性與功效性基本規範及技術文件摘要。

2、中央主管機關公告之品項，且製造業者曾有相同分類分級品項之類似品經中央主管機關核准上市者之醫療器材臨床前測試資料切結書。

(三)附表三之第二等級醫療器材，申請人曾取得由相同製造業者生產之同一品項類似品之許可證，且於有效期限者，除含藥醫療器材外，得以有類似品之第二等級醫療器材產品比較暨臨床前測試資料符合性聲明書替代之。

(四)經中央主管機關公告應辦理檢驗之醫療器材者，本項文件應檢附二份。

(五)執行檢測生物相容性、電性安全性、電磁相容性檢測及無菌

2. Import medical device raw material manufacturers or manufacturers issue descriptions and provide notarized documents from agents outside the country. After obtaining the notarization from foreign agents, they are to be transferred to agents in our country to apply for signature verification and affix the authorized agent’s signature to the application form, and provide the concerned agent’s business name, address, business registration number, and model specifications.

(3) The validity of this document is one year from the date of issue. If issued abroad, an English translation should be attached, along with the Chinese version or a notarized version.

Six. Medical device manufacturers must comply with the medical device quality management system certification documents:

(1) The document must be issued by the central competent authority certifying that the medical device manufacturer complies with the medical device quality management system principles and obtained a certification copy as proof.

(2) If originating abroad, it must be announced by the central competent authority. Such certification is valid for three years from the announcement date and can be substituted by documents that comply with the quality management principles of the foreign country.

Seven. Clinical trial test reports and raw material management system inspection reports, including raw material verification and testing records, must be submitted:

(1) This document includes studies related to maintaining product functionality, structure, material, design, and quality by conducting necessary safety and performance test reports.

(2) If the product is already approved by the central competent authority and registered for public sale as a secondary-class medical device, it must meet the following two criteria:

1. Collaborate with domestic representatives to check technical cooperation between a foreign government's official approval documents and safety basic specifications and related documentation.

2. Both the central competent authority’s approval documents and the manufacturer’s approval of a similar product must be mutually recognized as matching medical products for the clinical trial study data.

(3) The document appendix to the second-class devices on the list must show that the applicant has previously obtained approval from the manufacturer or is a sub-case of an existing approved product. Unless expired, excluding medical devices, the manufacturer can provide proof of the same item, counted by the authority.

(4) Through the central competent authority announcement of the specific management regulation of medical devices, a copy of this document must be attached in duplicate.

(5) Executing inspections for biological safety, electrical safety, electromagnetic compatibility tests, and sterile requirements.

Translated by RegDesk AI

性試驗之受託實驗室，應符合下列條件之一：

1、符合 ISO／IEC 17025 之規定。

2、符合非臨床試驗優良操作規範（GLP）之規定。

八、產品之結構、材料、規格、性能、用途、圖樣等有關資料：儀器類產品者，得以涵蓋本項資料之操作手冊及維修手冊替代之。

九、臨床證據資料：

(一)本項文件包括：

1、學術理論依據與有關研究報告及資料。

2、臨床評估報告或臨床試驗報告。

(二)申請查驗登記之醫療器材應否在國內進行臨床試驗，另由中央主管機關視申請之醫療器材品項、個案及申請人檢送之資料核辦或公告。

(三)已有類似品經中央主管機關核准上市者，除須以臨床證據佐證其安全及有效性者外，得免附之。

(四)第二等級且無類似品之醫療器材者，除另有規定外，得以符合下列所有條件之佐證資料替代臨床試驗報告：

1、該產品預期效能無種族差異。

2、該類產品宣稱之預期用途或適應症，未曾於國外有嚴重不良反應報告及未曾被要求下市。

3、該產品與國內已核准上市產品之不同處，可以經由臨床前資料(含試驗)證明其不影響產品之安全及有效性；或提供該產品已於美國及歐盟核准上市之證明文件，且其擬申請之適應症未超出美國及歐盟皆核准之範圍。

十、發生游離輻射器材之輻射防護安全資料：屬發生游離輻射之醫療器材者，應檢附本項文件。

十一、 醫療器材安全性與功效性基本規範及技術文件摘要：

(一)本項文件之格式，依中央主管機關公告者辦理。

(二)申請之第二等級醫療器材有說明七(二)1 情形者，應檢附本項文件。

十二、 原廠同一產品不同品名之說明函：應說明新申請產品與原核准

Experimental verification of physical tests should meet one of the following conditions:

1. Comply with the provisions of ISO/IEC 17025.

2. Comply with the provisions of Good Laboratory Practice (GLP) for non-clinical trials.

VIII. The composition, materials, specifications, performance, intended use, and graphic design of the product; the product category; the basic operation manuals and maintenance manuals of similar products may be substituted by existing reference materials.

IX. Clinical trial information:

(1) This document includes:

1. Relevant research reports and data based on academic theory.

2. Reports on clinical experience and clinical trials.

(2) For products that have been approved for clinical trials domestically, applicants need to submit relevant documents related to the product and submit inspection materials for each container for review by the regulatory authority.

(3) For products already in the market with approvals, the submission of clinical trial reports verifying their safety and effectiveness may be exempted.

(4) Second-level and unranked medical devices, unless otherwise specified, must meet all the following conditions to be exempt from clinical trial reports:

1. The product has a predetermined history and specifications.

2. The intended use and indications have not changed, and there have been no serious adverse reactions or unexpected requirements.

3. If approved abroad and listed, without affecting any safety and efficacy differences, clinical trial data (including raw data) should be accredited by U.S. or EU authorities and the applicant must include details in the range of indications not yet approved in the U.S. or the EU.

X. Safety test documents for amusement catheters and related materials should be submitted by the manufacturing company as per device categorization.

XI. Submission of basic safety and effectiveness standards, device documentation, or technical summaries:

(1) This document format should follow the publication guidelines of the relevant central authority.

(2) Applicants for second-class medical devices, in circumstances of subsection (2)(i), should submit documents accordingly.

XII. Explanation for differences in naming the same original product: An explanation is needed when product applications have different names compared to regulatory standards.

Translated by RegDesk AI

之產品係相同產品，並註明原核准之醫療器材許可證字號。

十三、 其他經中央主管機關指定之文件、資料：

(一)以牛、羊組織製成之醫療器材者，應檢附原廠之動物原料來源管制之作業說明及其原料來源證明，確保醫療器材相關製程與最終成品均未使用行政院農業委員會公告牛海綿狀腦病（Bovine Spongiform Encephalopathy）發生之國家（地區）之牛、羊來源產品，且未受牛海綿狀腦病病原污染。但經中央主管機關參考國際對含牛羊組織之管理規範，依據牛、羊組織受牛海綿狀腦病病原污染之危險程度高低而公告無須檢附前項資料者，不在此限。

(二)品名冠有商標者，應檢附商標註冊相關資料。品名冠有其他醫療器材商之名稱或商標者，應檢附被加冠者出具之同意函。

(三)為配合經濟部國際貿易局公告之限制輸入貨品及海關協助查核輸入貨品彙總表，輸入產地為中國之醫療器材，應先向經濟部國際貿易局取得准許輸入之證明文件，始得向中央主管機關申請查驗登記。

(四)專供外銷者，應檢附醫療器材之使用方法、功能、工作原理、產品組成(或成分)之說明，且其內容足以供認定該產品符合申請品項鑑別之資料。

(五)品名、標籤、說明書或包裝冠有特定國家或國際組織標準之性能規格專有名詞者，應檢附該地區國家、第三方驗證單位或國際組織出具之佐證文件。

十四、 送驗：依第三條第二項公告之品項，申請人應依送驗通知，於規定期限內繳納檢驗費，並檢附足供檢驗所需之樣品，辦理送驗手續。

Thirteen, other documents/materials approved by the central competent health authority:

(1) For medical devices made from cattle/sheep-derived materials, regarding their source, manufacturing process, and evidence that they are free from the risk of Bovine Spongiform Encephalopathy (BSE):

- Must include a statement and relevant information from the origin country of the animals, ensuring that BSE has not occurred, or if it has, the materials meet the requirements of low-risk as announced by the Veterinary Administration Council and in its official gazette.

(2) If the product is registered as a trademark, proof of the trademark registration and related documentation should be submitted. If the product is labeled with the trademark or product name of another medical device, additional documents or statements should be provided.

(3) Failure to comply with specific trade regulations as announced in international economic and trade public notices, the importer or local medical device manufacturer must comply with all regulations and provide proof of compliance with relevant documents as required by the central competent health authority.

(4) For devices supplemented with other materials, explain the functionality, working principles, and the composition (or components) of the product. Ensure the documentation matches the submitted product category information.

(5) The product name, labeling, instructions, and specification documentation issued by a designated organization or competent authority confirming compliance with relevant standards should be provided. The documents need certification by a third-party verification unit or an internationally recognized organization.

Ten, application: Based on Item 2 of Article 3 of the announcement, applicants must submit samples in accordance with the specified inspection period for testing, and also the required samples for other inspections stated in the announcement, and retain the transport documentation.

Page 89

Translated by RegDesk AI

附表三 第二等級醫療器材產品比較暨臨床前測試資料符合性聲明書之適用品項

	品項代碼	名稱
1	A.1020	酸性磷酸酶(總量或前列腺的)試驗系統
2	A.1025	促腎上腺皮質荷爾蒙試驗系統
3	A.1035	白蛋白試驗系統
4	A.1050	鹼性磷酸酶或同功酶試驗系統
5	A.1070	澱粉酶試驗系統
6	A.1110	膽紅素(總量或直接的)試驗系統
7	A.1150	校正品
8	A.1155	人類絨毛膜促性腺激素試驗系統
9	A.1215	肌酸磷酸激酶/肌酸激酶或同功酶試驗系統
10	A.1345	葡萄糖試驗系統
11	A.1660	品管材料(分析與非分析)
12	A.1675	血液樣本收集設備
13	B.5400	凝集儀器
14	B.5425	體外凝集研究之多功能系統
15	B.7470	糖(基)化血紅素分析
16	B.8625	血液學品質管制混合物
17	C.0002	登革病毒血清試劑
18	C.2410	奈瑟菌屬病原菌培養基
19	C.3305	單純皰疹病毒血清分析
20	C.3390	奈瑟氏菌屬直接血清試劑
21	C.3860	陰道滴蟲核酸檢驗試劑
22	C.5100	抗核抗體免疫試驗系統
23	C.5270	C 反應蛋白免疫試驗系統
24	C.5510	免疫球蛋白 A，G，M，D 及 E 免疫試驗系統
25	C.5750	放射性過敏原吸附免疫試驗系統

Table 3

Applicable Items for Second-Level Medical Device Product Comparison Clinical Pre-Test Data Meeting Compliance Certification Documents

Item Code | Name

1. A.1020 | Acid Phosphatase (Total or Prostatic) Test System
2. A.1025 | Pituitary Skin Function Tests Test System
3. A.1035 | Albumin Test System
4. A.1050 | Alkaline Phosphatase Isoenzymes Test System
5. A.1070 | Amylase Test System
6. A.1110 | Bilirubin (Total or Direct) Test System
7. A.1150 | Calibration Product
8. A.1155 | Human Chorionic Gonadotropin Test System
9. A.1215 | Creatine Kinase Isoenzymes/Creatine Kinase Isoenzymes Test System
10. A.1345 | Glucose Test System
11. A.1660 | Specimen Material (Analysis and Evaluation)
12. A.1675 | Blood Specimen Collection Device
13. B.5400 | Coagulation Instrument
14. B.5425 | External Coagulation Research Multifunction System
15. B.7470 | Sugars (Base) Blood Test System
16. B.8625 | Blood Quality Control Mixture
17. C.0002 | Dengue Fever Virus Blood Test Reagent
18. C.2410 | Naegleria fowleri Virus Culture Base
19. C.3305 | Pneumocystis Virus Blood Test Reagent
20. C.3390 | Naegleria fowleri Direct Blood Test Reagent
21. C.3860 | Vaginal Secretion Trichomonas Test System
22. C.5100 | Antibody Immune Test System
23. C.5270 | C-reactive Protein Immune Test System
24. C.5510 | Immunoglobulin A, G, M, D, E Test System
25. C.5750 | Radioallergosorbent Test System

Translated by RegDesk AI

26	C.5775	類風濕性因子免疫試驗系統
27	D.5630	噴霧器
28	D.5710	電動式氧氣帳
29	D.5730	氣管內管
30	D.5800	氣切管及其氣囊
31	D.5915	手動緊急呼吸器
32	E.0005	經皮穿刺冠狀動脈導管
33	E.1130	非侵入性血壓測量系統
34	E.1200	診斷用血管內導管
35	E.1210	連續性沖洗導管
36	E.1220	電極記錄導管或電極記錄探頭
37	E.1280	可操控導管
38	E.1310	經皮導管用血管擴張器
39	E.1330	導管導引線
40	E.1340	導管導引器
41	E.1650	血管攝影注射器和注射筒
42	E.2340	心電圖描記器
43	E.2360	心電圖用電極
44	E.2700	血氧飽和測定儀
45	E.2900	病患生理信號傳導器及電極線(包含連接線)
46	E.3450	血管移植彌補物
47	E.4450	血管夾
48	E.5150	血栓切除術導管
49	E.5900	熱調節系統
50	F.1745	雷射螢光齲蛀偵測器材
51	F.1800	口腔外X光照射系統
52	F.1810	口腔內X光照射系統
53	F.3060	牙科使用金基合金和貴重金屬合金
54	F.3200	樹脂牙黏劑

```plaintext
26 C.5775 Rubella Virus Genetic Testing System
27 D.5630 Spray Device
28 D.5710 Electric Oxygen Bladder
29 D.5730 Catheter
30 D.5800 Endotracheal Tube and Accessories
31 D.5915 Manual Emergency Resuscitator
32 E.0005 Percutaneous Coronary Artery Catheter
33 E.1130 Non-invasive Blood Pressure Measurement System
34 E.1200 Diagnostic Blood Vessel Catheter
35 E.1210 Continuous Irrigation Catheter
36 E.1220 Electrode Recording Catheter or Electrode Recording Sensor
37 E.1280 Steerable Catheter
38 E.1310 Percutaneous Catheter Balloon Angioplasty
39 E.1330 Catheter Guidewire
40 E.1340 Catheter Guiding Device
41 E.1650 Angiographic Injector and Syringe
42 E.2340 Electrocardiograph Recorder
43 E.2360 Electrocardiogram Electrodes
44 E.2700 Blood Oxygenation Measurement Device
45 E.2900 Patient Physiological Signal Transmitter and Electrode Wire (including Connection Wire)
46 E.3450 Vascular Transplantation Prosthesis
47 E.4450 Vascular Stent
48 E.5150 Blood Clot Removal Catheter
49 E.5900 Thermal Adjustment System
50 F.1745 Radiation-emitting Light Conductance Measurement Material
51 F.1800 Oral X-ray Imaging System
52 F.1810 Intraoral X-ray Imaging System
53 F.3060 Dental Alloy with Gold and Precious Metals
54 F.3200 Resin-based Dental Adhesive
```

Translated by RegDesk AI

55	F.3275	牙科用水泥(士敏汀)
56	F.3590	成形塑膠假牙床
57	F.3630	骨內植體用支台
58	F.3660	印模材料
59	F.3690	樹脂牙材
60	F.3765	凹窩封閉劑及調節劑
61	F.3820	根管充填樹脂
62	F.4760	骨板
63	F.4850	超音波洗牙機
64	F.6070	聚合用紫外線活化器
65	F.6660	牙科用瓷粉
66	G.4250	耳鼻喉電動式或氣動式外科鑽
67	H.1075	腸胃科-泌尿科生檢器械
68	H.1500	內視鏡及其附件
69	H.4620	輸尿管支架
70	H.5010	膽管用導管及其附件
71	H.5130	泌尿導管及其附件
72	H.5470	輸尿管擴張器
73	H.5540	血液通路裝置及其附件
74	H.5630	腹膜透析系統及其附件
75	H.5820	血液透析系統及其附件
76	H.5980	胃腸管及其附件
77	I.0003	超音波手術裝置
78	I.0006	醫用防護衣
79	I.4010	組織黏著劑
80	I.4014	外部使用非吸收式紗布或海綿球
81	I.4018	親水性創傷覆蓋材
82	I.4020	閉合用傷口/燒燙傷敷料
83	I.4022	水性創傷與燒傷覆蓋材

55 F.3275 Dental cement (silicate cement)

56 F.3590 Formed plastic prosthetic teeth

57 F.3630 Intrabony implant branch

58 F.3660 Impression materials

59 F.3690 Resin dental materials

60 F.3765 Cavity sealants and conditioners

61 F.3820 Root canal filling resins

62 F.4760 Bone plates

63 F.4850 Ultrasonic tooth cleaning machines

64 F.6070 Polymer ultraviolet activators

65 F.6660 Dental powders

66 G.4250 Electric or pneumatic external bone drills for ENT

67 H.1075 Gastrointestinal-urinary catheter biological inlays

68 H.1500 Endoscope and accessories

69 H.4620 Tubing and sheath sets

70 H.5010 Catheter balloons and accessories

71 H.5130 Urinary catheter balloons and accessories

72 H.5470 Urine tube expanders

73 H.5540 Bloodline setups and accessories

74 H.5630 Peritoneal dialysis systems and accessories

75 H.5820 Blood dialysis systems and accessories

76 H.5980 Gastrointestinal tubing and accessories

77 I.0003 Ultrasonic surgical devices

78 I.0006 Medical protective clothing

79 I.4010 Tissue adhesives

80 I.4014 External non-absorbent gauze or cotton balls

81 I.4018 Hydrophilic wound dressing materials

82 I.4020 Dressing materials for open wounds/burns

83 I.4022 Hydrophobic wound dressing materials

Translated by RegDesk AI

84	I.4370	外科手術用覆蓋巾及其附件
85	I.4400	切割及止血用電刀及其附件
86	I.4493	可吸收性交酯類外科用縫合線
87	I.4495	不銹鋼縫合線
88	I.4580	外科手術燈
89	I.4780	動力式抽吸幫浦
90	I.4810	一般外科、整形外科及皮膚科用雷射儀
91	I.4830	可吸收性腸縫合線
92	I.4840	可吸收性聚對二氧環己酮外科縫合線
93	I.5000	不可吸收性聚對苯二甲酸乙二酯縫合線
94	I.5010	不可吸收性聚丙烯縫合線
95	I.5020	不可吸收性聚醯胺縫合線
96	I.5030	不可吸收性絲縫合線
97	I.5035	非吸收式膨體聚四氟乙烯手術縫合線
98	J.2800	滅菌過程指示劑
99	J.2910	臨床電子體溫計
100	J.5090	液體性繃帶
101	J.5200	血管內導管
102	J.5240	醫療用黏性膠帶及黏性繃帶
103	J.5440	血管內輸液套
104	J.5570	皮下單腔針
105	J.5700	新生兒光照射治療裝置
106	J.5860	活塞式注射筒
107	J.5965	皮下植入式血管內注射口及導管
108	J.5970	經皮長期植入式血管內導管
109	J.6850	滅菌包
110	K.4305	動力合式頭顱鑽,銼子,環鋸及其附件
111	K.4310	動力簡易式頭蓋顱,銼子,環鋸及其附件
112	K.4360	電動頭顱鑽馬達

84	I.4370	Surgical cover and its accessories
85	I.4400	Cutting and hemostatic electrosurgery devices and accessories
86	I.4493	Absorbable antimicrobial surgical sutures
87	I.4495	Stainless steel sutures
88	I.4580	Surgical lamps
89	I.4780	Motorized suction devices
90	I.4810	General surgery, plastic surgery, and dermatology laser equipment
91	I.4830	Absorbable hernia sutures
92	I.4840	Absorbable polyglycolic acid surgical sutures
93	I.5000	Non-absorbable polyester surgical sutures
94	I.5010	Non-absorbable polypropylene surgical sutures
95	I.5020	Non-absorbable silk surgical sutures
96	I.5030	Non-absorbable nylon sutures
97	I.5035	Non-absorbable four-strand polyester surgical sutures
98	J.0090	Disinfection procedures
99	J.2800	Clinical thermometer
100	J.5090	Liquid feeding tube
101	J.5200	Blood vessel catheter
102	J.5240	Medical flexible belt and elastic belt
103	J.5440	Blood transfusion set
104	J.5570	Subcutaneous needle
105	J.5700	Neonatal phototherapy equipment
106	J.5860	Pre-filled injection syringe
107	J.5965	Subdermal or vascular injectable device and catheter
108	J.5970	Long-term implantable vascular catheter
109	J.6850	Sterilization package
110	K.4305	Power-assisted cranial drill, reamer, and accessories
111	K.4310	Simplified cranial drill, reamer, and accessories
112	K.4360	Electric cranial drill system

93

Translated by RegDesk AI

113	K.4370	氣動頭顱鑽馬達
114	K.4840	手動式骨鉗
115	L.1690	子宮鏡及其附件
116	L.1720	婦產科用腹腔鏡及其附件
117	L.1730	腹腔鏡灌入器
118	L.4150	雙極內視鏡凝結-切割器及其附件
119	L.6100	輔助生殖之導引針
120	L.6110	輔助生殖導管
121	L.6130	輔助生殖之微小器具
122	M.1120	眼科攝影機
123	M.1570	眼底鏡
124	M.1850	交流電力式細隙燈
125	M.4150	玻璃體吸引及切割器械
126	M.4670	晶體乳化儀
127	M.4790	眼科用海棉
128	M.5918	硬式透氣隱形眼鏡保存用產品
129	M.5925	軟式隱形眼鏡
130	M.5928	軟式隱形眼鏡保存用產品
131	N.1100	關節鏡
132	N.3027	PMMA 骨水泥
133	N.3045	可吸收鈣鹽骨洞填充裝置
134	N.3050	椎弓板間之脊椎矯正固定物
135	N.3060	椎體間之脊椎矯正固定物
136	N.3070	椎弓螺釘系統
137	O.0001	靜電器(電位治療器)
138	O.3860	動力式輪椅
139	O.5500	紅外線燈
140	P.1570	診斷用超音波轉換器

```plaintext
113  K.4370  Pneumatic Head Frame Marlette
114  K.4840  Manual Bone Drill
115  L.1690  Hysteroscope and Accessories
116  L.1720  Obstetrics and Gynecology Laparoscope and Accessories
117  L.1730  Laparoscope Inserter
118  L.4150  Bipolar Endoscope Coagulation-Cutting Instruments and Accessories
119  L.6100  Assisted Reproduction Guiding Needle
120  L.6110  Assisted Reproduction Guide Tube
121  L.6130  Assisted Reproduction Microsurgical Instruments
122  M.1120  Ophthalmic Camera
123  M.1570  Ophthalmoscope
124  M.1850  AC Electric Fine Slit Lamp
125  M.4150  Glass Cutter and Divider
126  M.4670  Crystal Emulsification Instrument
127  M.4790  Ophthalmic Laser
128  M.5918  Hard Gas Permeable Contact Lens Care Product
129  M.5925  Soft Contact Lenses
130  M.5928  Soft Contact Lens Care Products
131  N.1100  Arthroscope
132  N.3027  PMMA Bone Cement
133  N.3045  Absorbable Bone Cavity Filling Device
134  N.3050  Intervertebral Disc Traction Fixation Device for Vertebral Plate
135  N.3060  Intervertebral Disc Traction Fixation Device for Spine
136  N.3070  Spinal Screw Fixation System
137  O.0001  Static Device (Electric Treatment Device)
138  O.3860  Dynamic Wheelchair
139  O.5500  Infrared Lamp
140  P.1570  Diagnostic Ultrasound Transducer
```

Translated by RegDesk AI

附表四 申請醫療器材許可證變更、補發或換發應檢具之文件、資料

變更項目 / 應檢附文件、資料項目		中文品名	英文品名	原廠標籤、說明書或包裝	成分、材料、結構、規格或型號	效能、用途或適應症	製造業者名稱	製造業者地址或製造國別	許可證所有人	許可證所有人名稱	遺失補發或污損換發	製造許可編號
1	醫療器材變更登記申請書	○	○	○	○	○	○	○	○註9	○	○	○
2	醫療器材查驗登記申請書	╳	╳	╳	╳	╳	╳	╳	╳	╳	△註13	╳
3	原許可證正本	○	○	○	○	○	○	○	○	○	△註14	○

Appendix 4 Application for Changes to Medical Device Permit, and Documentation for Supplementary or Replacement Issuance Inspection

Change Item	Product Name in Chinese	Pro... Name in Eng...	Orig... Appr.. Numb	Instruct... Specific... or Colors	Composition, Material, Structure, Specifications or Model Number	Inte... Use, Indi...	Manufactu Name or Manufactu Address	Ma.. Map	Perm. Numb Coll...	Per.. Hol.. Nam	Loss, Suppl... Repla...
Requi... Docum.. or Data Item											
1	Application for Change to Medical Device Record	○	○	○	○	○	○	○	○	Note 9	
2	Application for Review of Medical Device Record	×	×	×	×	×	×	×	△	Note 13	
3	Original Permit Copy	○	○	○	○	○	○	○	△	Note 14	○

95

Translated by RegDesk AI

4	原核准並蓋有中央主管機關核定章之標籤、說明書或包裝正本	╳	╳	○	△註2	○	╳	╳	╳	╳	△註15	╳
5	標籤、說明書或包裝擬稿二份	╳	╳	○	△註3	○	╳	╳	╳	╳	△註16	╳
6	醫療器材商許可執照影本	╳	╳	╳	╳	╳	△註5	△註5	○註10	○註12	╳	╳
7	出產國許可製售證明正本	╳	△註1	╳	△註4	△註4	△註4	△註6	╳	╳	╳	╳
8	國外原廠授權登記書正本	╳	╳	╳	△註4	△註4	△註4	△註4	△註11	╳	╳	╳
9	醫療器材製造業者符合醫療器材品質管理系統準則之證明文件	╳	╳	╳	╳	╳	○	○	╳	╳	╳	○

Unapproved patents or summary of device specifications and packaging in original form (4)	○	×	△ **(N… 2)**	×	○	×	×	×	×	△ **(No… 15)**	×	
Specifications and packaging in original form duplicate copies (5)	×	×	△ (N… 3)	○	○	×	×	×	×	△ (No… 16)	×	
Medical device manufacturer's conformity materials or a copy of permit (6)	×	×	△ (N… 5)	◯	△ (N… 5)	×	△ (No… 10)	◯	×	△ (No… 12)	×	
Permit for domestic production and sales license in original form (7)	△ (N… 1)	×	△ (N… 4)	△ (N… 4)	△ (N… 4)	×	×	×	×	×	×	
Overseas original manufacturing permit registration in original form (8)	×	×	△ (N… 4)	△ (N… 4)	△ (N… 4)	×	△ (No… 11)	×	×	×	×	×
Medical device manufacturer's medical device quality management system certification documents (9)	×	×	×	×	×	○	×	○	×	×	○	

Note: (×) means not applicable, (○) required, (△) conditionally applicable depending on note.

Translated by RegDesk AI

10	臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書	╳	╳	╳	△註3	○	╳	△註7註8	╳	╳	╳	╳
11	產品之結構、材料、規格、性能、用途、圖樣等有關資料	╳	╳	╳	△註3	○	╳	△註7註8	╳	╳	╳	╳
12	臨床證據資料	╳	╳	╳	△註3	△	╳	╳	╳	╳	╳	╳
13	發生游離輻射器材之輻射防護安全資料	╳	╳	╳	△註3	╳	╳	╳	╳	╳	╳	╳
14	原廠變更說明函	╳	○	○	△註3	○	○	○	╳	╳	╳	╳
15	擬變更之內容與原核准者之比較表	╳	╳	○	△註3	○	╳	╳	╳	╳	╳	╳

Clinical test samples and regulations, original quality inspection methods, original specifications, test records and test result reports	△	X	X	X	△	... 3	◯	X	△	... 7	... 8	X	X	X	X
Product structure, material, specifications, performance, use, diagrams, and related information	△	X	X	X	△	... 3	◯	X	△	... 7	... 8	X	X	X	X
Clinical investigation information	△	X	X	X	△	... 3	X	X	X	X	X	X	X	X	
Information for sterilization method and radiation protection of biological separation materials	△	X	X	X	△	... 3	X	X	X	X	X	X	X	X	
Original version change explanation document	△	X	◯	◯	◯	△	... 3	◯	◯	◯	◯	X	X	X	X
Comparison table between changed and original version approvers	△	X	X	X	△	... 3	X	X	X	X	X	X	X	X	

97

Translated by RegDesk AI

16	讓與人及受讓人共同出具之讓與聲明書	╳	╳	╳	╳	╳	╳	╳	○	╳	╳	╳
17	受讓許可證之醫療器材商(受讓人)對受讓醫療器材負責之聲明書	╳	╳	╳	╳	╳	╳	╳	○	╳	╳	╳
18	名稱變更後之醫療器材商出具對變更許可證之各該醫療器材負責之聲明書	╳	╳	╳	╳	╳	╳	╳	╳	○	╳	╳
19	醫療器材商名稱變更未涉許可證讓與之聲明書	╳	╳	╳	╳	╳	╳	╳	╳	○	╳	╳
20	其他經中央主管機關指定之文件、資料	△	△	△	△	△	△	△	△	△	△ 註17	△

16	**Certifying document for the entrusting party and party being entrusted, including their annual concurrent certificates**
17	Certification for the entrusting party authorized to offer medical devices (recipient) or medical material to the recipient
18	Certification for the substitution party post-title change of the medical device brand or license of various medical materials
19	Certification for the change of name or brand of medical material including authorization
20	Relevant documents or data designated by the main overseeing agency among other organizations
Note 17	

Translated by RegDesk AI

21	送驗	╳	╳	╳	△ 註 18	╳	╳	△ 註 18	╳	╳	╳	╳

說明：

一、○：表示須檢附該項目之資料。△：表示視個案而定。╳：表示不須檢附該項目之資料。

二、標籤、說明書或包裝擬稿、醫療器材商許可執照影本、出產國許可製售證明、國外原廠授權登記書、醫療器材製造業者符合醫療器材品質管理系統準則之證明文件、臨床前測試及原廠品質管制之檢驗規格與方法、原始檢驗紀錄及檢驗成績書、產品之結構、材料、規格、性能、用途、圖樣等有關資料、臨床證據資料、發生游離輻射器材之輻射防護安全資料、其他經中央主管機關指定之文件、送驗之相關規定，請參見附表二之說明項。

註：

1. 出產國許可製售證明應可辨識變更後之產品與原核准相同。國產醫療器材者，免附。
2. 規格變更如屬未涉及原核准之標籤、說明書或包裝變更者，免附。
3. 刪除規格者，免附。
4. 國產醫療器材者，免附。刪除規格者，免附。
5. 國產醫療器材者，檢附新廠之醫療器材製造業許可執照影本。輸入醫療器材者，免附。
6. 國產醫療器材者，免附。製造業者地址變更如係因門牌整編者，得免附本項文件，但應檢附政府機關出具之證明文件，其屬輸入醫療器材者，並應經我國駐外館處驗證。
7. 申請變更如係第三等級體外診斷醫療器材者，應檢附本項資料；其他產品之變更，必要時，中央主管機關得命提出。
8. 經中央主管機關公告應辦理檢驗之醫療器材者，本項文件應檢附二份。
9. 許可證所有人變更應由讓與人及受讓人雙方共同申請。

21 Variation

Explanation:

□□○: Indicates items or information that must be attached. △: Indicates that it depends on individual cases. X: Indicates that no attachment of items or information is necessary.

□□The label, instruction, or packaging: Medical equipment must attach a photocopy of overseas production permit, overseas manufacturer authorization certificate, medical material manufacturer meeting medical material quality management system standards certification documents, clinical evaluation reports, and original permit holder's proof of raw material source or certificate of analysis and testing methods, original permit holder's product composition, product structure, material, specification, characteristics, usage, and relevant domestic and foreign information, clinical evaluation information, in vitro diagnostic medical equipment and relevant safety information, along with documents required by the central competent authority. For related rules on variation, please refer to List 2 and the explanatory notes.

Notes:

1. A photocopy of the overseas production permit must be attached, or a document identifying the original permit holder and the recognized standard. For domestic manufacturers, this is exempt.

2. If a variation involves process or raw material standards, an explanation or except for a replacement is needed; this is exempt.

3. This does not apply to abolished standards.

4. Domestic medical equipment manufacturers and importers are exempt; this does not apply.

5. Domestic medical material manufacturers submitting a new classification code for review according to the medical device regulations; exempt from photocopy.

6. Domestic medical material manufacturers are exempt; the original permit holder is exempt from editing the variation part, but national and central competent authorities must be attached with relevant documents and other identified variations. The central competent authority will review and approve.

7. Applicants applying for third-class implantable diagnostic medical equipment's classification variation need to attach relevant documents. The central competent authority will assist in interpretation.

8. A public notice from the central competent authority will exempt documents for medical equipment variations that require attached information or full approval.

9. All approved variations must be jointly filed by the original permit holder and the recipient of the original permit.

Translated by RegDesk AI

10. 指受讓人之醫療器材商許可執照影本。
11. 國外原廠授權登記書應詳述終止讓與人之登記權利，改由受讓人登記，並應詳列品名、讓與人及受讓人雙方名稱、地址。國產醫療器材者，免附。
12. 指名稱變更後之醫療器材商許可執照影本。
13. 申請許可證污損換發或遺失補發者，應檢附本項文件。申請標籤、說明書或包裝污損換發或遺失補發者，免附。
14. 申請許可證遺失補發者，免附。
15. 申請標籤、說明書或包裝污損換發者，應檢附本項文件。申請許可證污損換發或遺失補發者及標籤、說明書或包裝遺失補發者，免附。
16. 申請標籤、說明書或包裝污損換發或遺失補發者，應檢附本項文件。申請許可證污損換發或遺失補發者，免附。
17. 申請許可證遺失補發者，應檢附聲明原許可證確係遺失之聲明書。申請標籤、說明書或包裝遺失補發者，應檢附聲明原標籤、說明書或包裝確係遺失之聲明書。
18. 申請人應依送驗通知，於規定期限內繳納檢驗費，並檢附足供檢驗所需之樣品，辦理送驗手續。

10. Medical personnel and medical device materials may be photographed after designation.

11. The consent form signed by the subject from a foreign language may be photographed after medical personnel transcribe it into detailed notes. The original should be signed, the lot number should be changed to the subject’s signature, and the subject’s name and address should be entered. Photos of biological and medical device materials are exempt.

12. After naming and registration, medical personnel may be photographed with their name.

13. Applicants who request to sign, annotate, or request reports, should attach this project's document. Applicants who are unable to sign, annotate, or explain the omission are exempt.

14. Applicants who request reports are exempt from additional annotations.

15. Applicants who request to annotate or request reports, should attach this project's document. Applicants who are unable to sign, annotate, or explain the omission are exempt.

16. Applicants who request, annotate, or report annotations are exempt.

17. Applicants who request reports and have the original attached thereto, and who are unable to annotate or explain the original omission.

18. After the applicant is subject to inspection by a certain time limit, they may request a detailed inspection and may also provide a handover.

Translated by RegDesk AI

附表五 登錄製造、輸入第一等級醫療器材應上傳之備查文件、資料

項目		上傳情形
1	醫療器材商許可執照影本	○
2	醫療器材製造業者符合醫療器材品質管理系統準則之證明文件	△
3	原廠產品說明書資料	△
4	臨床前測試之檢驗規格與方法及檢驗成績書	△
5	其他經中央主管機關指定之文件、資料	△

說明：

一、○：表示須檢附該項目之資料。△：表示視個案而定。

二、醫療器材商許可執照影本：

(一) 製造醫療器材者，應上傳醫療器材製造業許可執照影本。輸入醫療器材者，應上傳營業項目包含“輸入”之醫療器材販賣業許可執照影本。

(二) 國內委託製造者，應上傳委託者及受託製造業者之醫療器材商許可執照。

三、醫療器材製造業者符合醫療器材品質管理系統準則之證明文件：本項文件指由中央主管機關核發之醫療器材製造業者符合醫療器材品質管理系統準則之證明文件影本。但經中央主管機關公告免取得製造許可之品項，免附。

四、原廠產品說明書資料：應包含醫療器材之使用方法、功能、工作原理、產品組成(或成分)之說明，且其內容足以供認定該醫療產

Appendix 5 Documents and Materials for Upload Review for Registration, Manufacture, and Importation of Class I Medical Devices

Item	Upload Condition
1. Copy of Medical Device Manufacturing License	○
2. Documents proving compliance with the quality management system regulations for medical device manufacturers	△
3. Original product description materials	○
4. Performance test specifications and performance test reports before clinical use	△
5. Other documents designated by the central competent authority	△

Notes:

I. ○: Indicates the required documents for this item. △: Determined on a case-by-case basis.

Ⅱ. Copy of Medical Device Manufacturing License:

(1) Manufacturers: The manufacturing license of the final manufacturing or importing medical device company, uploaded as a copy of the "Import" section.

(2) National commissioned manufacturers: The manufacturing license of the entrusted recipient and commissioned manufacturers must be uploaded.

Ⅲ. Documents proving compliance with quality management system regulations for medical device manufacturers:

This document is specified by the central competent authority for examining whether the medical device manufacturer complies with the quality management system regulations. However, if exempted by the central competent authority, it is not required to be attached.

Ⅳ. Original product description materials:

Should contain explanations of the methods of use, functions, working principles, and composition (ingredients) of medical devices, ensuring the content is sufficient to support the stated performance of the medical device.

Page 101

Translated by RegDesk AI

品符合第一等級品項鑑別之資料。屬登錄系統指定之品項，應上傳本項文件。

五、臨床前測試之檢驗規格與方法及檢驗成績書：第一等級醫療器材品項鑑別或經中央主管機關依本法第三十條公告，對於產品性能規格有規定者，應上傳本項文件。

六、其他經中央主管機關指定之文件、資料：

（一）品名冠有商標者，應上傳商標註冊相關資料。品名冠有其他廠商之名稱或商標者，應上傳被加冠者出具之同意函。

（二）為配合經濟部國際貿易局公告之限制輸入貨品及海關協助查核輸入貨品彙總表，輸入產地為中國之醫療器材，應先向經濟部國際貿易局取得准許輸入之證明文件，始得向中央主管機關申請登錄。

（三）品名冠有特定國家或國際組織標準之性能規格專有名詞者，應上傳該地區國家、第三方驗證單位或國際組織出具之佐證文件。

This translation requires understanding and context related to regulatory terms, which may vary. Here's the structured translation of the text you provided:

□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□□□□

(□) □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□□□□□□□□

(□) □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□

(□) □□□□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□□□□□□□□□□□□□□□□□□□□□□□□□

□□□

Compliant with documents related to the first grade item category. For items specified in the registration system, this document must be uploaded.

5. Preclinical test specifications or test method and inspection performance report: For first-grade medical equipment.

Items must comply with the announcement of Article 30 of this Act by the central competent authority. For products with performance specifications regulations, this document must be uploaded.

6. Other documents and materials designated by the central competent authority:

(1) If the product name bears a trademark, the relevant trademark registration information must be uploaded. If the product name bears the name or trademark of another manufacturer, a consent form issued by the crowned party must be uploaded.

(2) To comply with the Ministry of Economic Affairs International Trade Bureau announcement of restrictions on imported goods and customs assistance in verifying imported goods measures, for medical devices with the place of origin of China, a permit for entry issued by the Ministry of Economic Affairs International Trade Bureau must be obtained first, before applying to the central competent authority for registration.

(3) If the product name bears records of specific countries or international organization standards for performance specifications, supporting documents issued by the local country, a third-party testing organization, or an international organization must be uploaded.

Translated by RegDesk AI

【特定醫療器材專案核准製造及輸入辦法】(110.04.22發布)

第1條

本辦法依醫療器材管理法（以下稱本法）第三十五條第二項規定訂定之。

第2條

依本法第三十五條第一項各款規定，向中央主管機關申請醫療器材專案核准製造或輸入者，應具備下列資格、條件：

一、第一款：區域醫院以上之教學醫院或精神科教學醫院。

二、第二款：政府機關、學校、機構、法人或團體。

三、第三款：醫療器材商、藥商或臨床試驗機構。

四、第四款：

（一）使用樣品之政府機關、學校、機構、法人或團體。

（二）捐贈贈品之政府機關、學校、機構、法人、團體、自然人或商號。

（三）使用專供個人自用醫療器材之自然人。

五、第五款：從事維修之醫療器材販賣業者（以下簡稱維修業者）。

六、第六款：醫療器材商。

第3條

前條第四款第一目樣品，指符合下列各款情形之一之醫療器材：

一、醫療器材商申請供查驗登記送驗之用。

二、醫療器材製造業者專供改進製造技術之用。

三、醫療器材商、藥商、研究機構、試驗機構或教學醫院，專供體外研究或非屬臨床試驗之用。

四、醫療器材商或展示主辦單位專供特定展示之用。

五、許可證所有人或登錄者專供宣導之用，且其包裝量少於原查驗登記或登錄之最小包裝量。

前項第三款體外研究，指不用於人體，且不涉及醫療診斷、治療或臨床處置，進行醫療器材本體性能之研究。

第4條

第二條第四款第二目贈品，指因應公共安全、公共衛生或重大災害，捐贈作為慈善目的用之醫療器材。

第5條

第二條第四款第三目專供個人自用，指無需由醫師或專業人員操作，由自

103

“Regulations Governing Special Project Approval for the Manufacture and Importation of Designated Medical Devices” (Promulgated 2021.04.22)

Article 1

These Regulations are enacted pursuant to Article 35, Paragraph 2 of the Medical Devices Act (hereinafter referred to as “the Act”).

Article 2

Applicants seeking special project approval for the manufacture or importation of medical devices from the central competent authority in accordance with each subparagraph of Paragraph 1, Article 35 of the Act must possess the following qualifications and conditions:

1. Subparagraph 1: Regional teaching hospitals or psychiatric teaching hospitals and above.

2. Subparagraph 2: Government agencies, schools, institutions, juridical persons, or organizations.

3. Subparagraph 3: Medical device businesses, pharmaceutical businesses, or clinical trial institutions.

4. Subparagraph 4:

(1) Government agencies, schools, institutions, juridical persons, or organizations using samples.

(2) Government agencies, schools, institutions, juridical persons, organizations, natural persons, or firms donating gifts.

(3) Natural persons using specifically designated medical devices for personal use.

5. Subparagraph 5: Medical device vendors engaged in maintenance (hereinafter referred to as “maintenance vendors”).

6. Subparagraph 6: Medical device businesses.

Article 3

Samples under Subparagraph 4, Item 1 of the preceding Article refer to medical devices that meet any of the following conditions:

1. Medical device businesses apply for the purpose of registration inspection and testing.

2. Medical device manufacturers apply exclusively for the purpose of improving manufacturing technology.

3. Medical device businesses, pharmaceutical businesses, research institutions, experimental institutions, or teaching hospitals apply exclusively for in vitro research or non-clinical trial purposes.

4. Medical device businesses or exhibition organizers apply exclusively for specific exhibitions.

5. License holders or registrants apply exclusively for promotional purposes, and the packaging quantity is less than the minimum packaging quantity of the original registration or listing.

“In vitro research” as stipulated in Item 3 of the preceding paragraph refers to research on the intrinsic performance of medical devices that is not used on the human body, does not involve medical diagnosis, treatment, or clinical intervention.

Article 4

“Gifts” under Article 2, Subparagraph 4, Item 2 refer to medical devices donated for charitable purposes in response to public safety, public health, or major disasters.

Article 5

Translated by RegDesk AI

“Specifically designated for personal use” under Article 2, Subparagraph 4, Item 3 refers to devices that do not require operation by a physician or professional personnel and are used by the individual themselves.

Translated by RegDesk AI

然人自行使用之醫療器材。

第6條

申請特定醫療器材專案製造或輸入者，應填具申請書，並檢附第八條至第十九條規定之文件、資料，及繳納費用，向中央主管機關提出。

前項文件、資料，應以正體中文書寫；非正體中文者，應檢附正體中文或英文譯本。

第一項申請，其申請書或文件、資料有闕漏或不完備而得補正者，中央主管機關得通知限期補正，並以一次為限；未於期限內補正或補正不完備者，得逕予駁回。

第一項醫療器材符合下列規定之一者，得以中央主管機關公告之便捷通關管理方式輸入，不受前三項規定之限制：

一、專供個人自用，且符合附表所列項目及數量。

二、臨床試驗用，且屬檢體採集耗材套組。

前項第一款情形，除入境旅客自行攜入者外，其經便捷通關方式輸入之次數，以每半年一次為限。

第7條

前條第一項申請之數量，應符合下列規定：

一、供改進技術、特定展示之儀器類，同一型號以一部（個）為限。但供不同展場、檢測需要或其他特殊情形，不在此限。

二、專供個人自用之耗材類，其數量以六個月用量為限。

三、專供個人自用之儀器類，同一型號以一部（個）為限。但有於不同地點使用或有其他特殊情形必要者，不在此限。

第8條

第二條第一款醫院申請製造或輸入醫療器材者，其應檢附之文件、資料如下：

一、診斷證明書及病歷。

二、醫院人體研究倫理審查委員會之核准使用證明。

三、完整治療計畫書及相關文獻依據。

四、病人同意書，其內容應載明該醫療器材係未取得中央主管機關許可證或登錄者。

五、申請數量及計算依據。

六、醫療器材使用說明書。

七、醫療器材結構、規格、性能、用途、圖樣、製造品質資料、安全性與效

104

Self-use medical devices.

Article 6

Applicants for special project-based manufacturing or importation of specific medical devices shall fill out an application form, attach the documents and information stipulated in Articles 8 to 19, and pay the required fees to the central competent authority.

The documents and information specified in the preceding paragraph must be written in Traditional Chinese; if not in Traditional Chinese, a translation in Traditional Chinese or English must be attached.

If there are omissions or deficiencies in the application form, documents, or information submitted under Paragraph 1 that can be corrected, the central competent authority may notify the applicant to make corrections within a specified period, limited to one instance only. If the applicant fails to correct the deficiencies within the prescribed period or if the corrections remain incomplete, the application may be dismissed directly.

If the medical device in Paragraph 1 meets one of the following criteria, it may be imported under the streamlined customs clearance management method as announced by the central competent authority, without being subject to the restrictions of the preceding three paragraphs:

1. Exclusively for personal use, and in compliance with the items and quantities listed in the attached table.

2. For clinical trial use, and is a specimen collection consumable kit.

In the situation described in Subparagraph 1 of the preceding paragraph, except for inbound travelers personally carrying the items, the frequency of importation through the streamlined customs clearance method shall be limited to once every six months.

Article 7

The quantity applied for under Paragraph 1 of the preceding article shall comply with the following regulations:

1. For devices used to improve technology or for specific exhibitions, one unit (item) of the same model is permitted. However, this limit does not apply to different exhibition venues, testing requirements, or other special circumstances.

2. For consumables exclusively for personal use, the quantity is limited to a six-month supply.

3. For instruments exclusively for personal use, one unit (item) of the same model is permitted. However, if there is a necessity for usage at different locations or other special circumstances, this limit does not apply.

Article 8

For hospitals applying for the manufacture or import of medical devices as specified in Subparagraph 1 of Article 2, the following documents and information must be attached:

1. Medical certificate of diagnosis and medical records.

2. Approval for use from the hospital institutional review board (IRB) for human research ethics.

3. Complete treatment plan and relevant supporting literature.

4. Patient consent form, which must state that the medical device in question has not obtained a permit or registration from the central competent authority.

5. Applied quantity and the basis for its calculation.

Translated by RegDesk AI

6. Instructions for use of the medical device.

7. Data on the structure, specifications, performance, purpose, drawings, manufacturing quality, safety, and efficacy of the medical device.

Translated by RegDesk AI

能試驗報告、人體使用資料及風險利益評估報告。

前項第一款及第二款內容，應載明申請目的為預防、診治危及生命或嚴重失能之疾病，且國內尚無合適替代療法之意旨。

第一項第一款病歷、第二款證明及第四款病人同意書，得於申請或使用後三十日內補具。

第一項第七款文件、資料，得以醫療器材之國外政府核准製造銷售證明替代。

第9條

第二條第二款政府機關、學校、機構、法人或團體申請製造或輸入醫療器材者，其應檢附之文件、資料如下：

一、因應緊急公共衛生情事之說明文件。

二、申請數量及計算依據。

三、醫療器材使用說明書。

四、醫療器材結構、規格、性能、用途、圖樣、製造品質資料、安全性與效能試驗報告、人體使用資料及風險利益評估報告。

五、國內製造者，另檢附工廠登記證資料。但依工廠管理輔導法規定免辦理工廠登記者，不在此限。

前項第四款文件、資料，得以醫療器材之國外政府核准製造銷售證明或中央主管機關指定文件、資料替代。

第10條

第二條第三款醫療器材商、藥商或臨床試驗機構申請製造或輸入醫療器材者，其應檢附之文件、資料如下：

一、申請者資格文件：

（一）醫療器材商或藥商：許可執照影本。

（二）臨床試驗機構：機構設立證明文件；其申請書蓋印信者，免附。

二、臨床試驗倫理審查委員會同意書。

三、試驗用醫療器材之結構、規格、性能、用途、圖樣及其他相關資料。

四、試驗用醫療器材之安全及效能相關試驗資料。

五、臨床試驗計畫書。

六、受試者同意書。

七、申請數量及計算依據。

前項第四款資料，得以醫療器材之原產國政府核准製造銷售證明替代。

105

Test reports, human use data, and risk-benefit assessment reports.

The contents of item 1 and item 2 of the preceding paragraph shall specify that the purpose of the application is for the prevention, diagnosis, or treatment of life-threatening diseases or diseases causing severe disability, and that there are currently no suitable alternative therapies available domestically.

The medical records under item 1, the certification under item 2, and the patient consent form under item 4 of paragraph 1 may be supplemented within thirty days after application or use.

The documentation and data under item 7 of paragraph 1 may be replaced with certification of foreign government approval for the manufacture and sale of the medical device.

Article 9

For government agencies, schools, institutions, legal persons, or organizations applying to manufacture or import medical devices under Article 2, Paragraph 2, the documents and data that shall be submitted are as follows:

1. Explanation documents in response to emergency public health events.

2. The quantity applied for and calculation basis.

3. Instructions for use of the medical device.

4. Medical device structure, specifications, performance, purpose, drawings, manufacturing quality data, safety and efficacy test reports, human use data, and risk-benefit assessment reports.

5. For domestic manufacturers, additional factory registration certificate data shall be submitted. However, those exempted from factory registration in accordance with the Factory Management and Counseling Act are not subject to this requirement.

The documentation and data under item 4 of the preceding paragraph may be substituted with certification of foreign government approval for the manufacture and sale of the medical device or specific documents/data designated by the central competent authority.

Article 10

For medical device dealers, pharmaceutical dealers, or clinical trial institutions applying to manufacture or import medical devices under Article 2, Paragraph 3, the documents and data that shall be submitted are as follows:

1. Applicant qualification documents:

(1) Medical device dealer or pharmaceutical dealer: Copy of license.

(2) Clinical trial institution: Institutional establishment certificate; if the application form bears the institution’s official seal, the certificate need not be attached.

2. Approval from a clinical trial ethics review committee.

3. Structure, specifications, performance, purpose, drawings, and other relevant data of the investigational medical device.

4. Data relating to the safety and efficacy studies of the investigational medical device.

5. Clinical trial protocol.

6. Subject consent form.

7. The quantity applied for and calculation basis.

Translated by RegDesk AI

The data under item 4 of the preceding paragraph may be replaced with certification of manufacturing and sales approval from the government of the country of origin of the medical device.

Translated by RegDesk AI

第11條

第三條第一項第一款醫療器材商申請製造或輸入醫療器材樣品者，其應檢附之文件、資料如下：

一、中央主管機關通知查驗登記送驗之公文。

二、申請數量及計算依據。

三、醫療器材使用說明書。

第12條

第三條第一項第二款醫療器材製造業者申請製造或輸入醫療器材樣品者，其應檢附之文件、資料如下：

一、醫療器材製造業許可執照影本。

二、改進製造計畫書。

三、申請數量及計算依據。

四、醫療器材使用說明書。

第13條

第三條第一項第三款醫療器材商、藥商、研究機構、試驗機構或教學醫院申請製造或輸入醫療器材樣品者，其應檢附之文件、資料如下：

一、申請者資格文件：

（一）醫療器材商或藥商：許可執照影本。

（二）研究機構、試驗機構或教學醫院：機構設立證明文件；其申請書蓋印信者，免附。

二、研究計畫書。

三、醫療器材使用說明書。

四、申請數量及計算依據。

第14條

第三條第一項第四款醫療器材商或展示主辦單位申請製造或輸入醫療器材樣品者，其應檢附之文件、資料如下：

一、醫療器材商許可執照影本，或展示主辦單位登記或設立證明。

二、醫療器材使用說明書。

三、主辦單位出具載有醫療器材商名稱、展示活動名稱、時間、地點之證明文件。

四、申請數量及計算依據。

第15條

第三條第一項第五款許可證所有人或登錄者申請製造或輸入醫療器材樣品

Article 11

For medical device dealers applying for the manufacture or import of medical device samples pursuant to Article 3, Paragraph 1, Subparagraph 1, the following documents and information shall be submitted:

1. Official notification from the central competent authority regarding the request for inspection and registration.

2. Quantity requested and the basis for calculation.

3. Medical device instructions for use.

Article 12

For medical device manufacturers applying for the manufacture or import of medical device samples pursuant to Article 3, Paragraph 1, Subparagraph 2, the following documents and information shall be submitted:

1. Photocopy of the medical device manufacturer’s license.

2. Manufacturing improvement plan.

3. Quantity requested and the basis for calculation.

4. Medical device instructions for use.

Article 13

For medical device dealers, pharmaceutical dealers, research institutions, testing institutions, or teaching hospitals applying for the manufacture or import of medical device samples pursuant to Article 3, Paragraph 1, Subparagraph 3, the following documents and information shall be submitted:

1. Applicant qualification documents:

(1) Medical device dealers or pharmaceutical dealers: Photocopy of the license.

(2) Research institutions, testing institutions, or teaching hospitals: Certificate of establishment of the institution; if the application is stamped with the institution’s seal, this may be omitted.

2. Research project plan.

3. Medical device instructions for use.

4. Quantity requested and the basis for calculation.

Article 14

For medical device dealers or exhibition organizers applying for the manufacture or import of medical device samples pursuant to Article 3, Paragraph 1, Subparagraph 4, the following documents and information shall be submitted:

1. Photocopy of the medical device dealer’s license, or proof of registration or establishment for the exhibition organizer.

2. Medical device instructions for use.

3. Proof issued by the organizer with the medical device dealer’s name, exhibition event name, time, and location.

4. Quantity requested and the basis for calculation.

Article 15

Translated by RegDesk AI

For license holders or registrants applying for the manufacture or import of medical device samples pursuant to Article 3, Paragraph 1, Subparagraph 5...

Translated by RegDesk AI

者，其應檢附之文件、資料如下：

一、醫療器材商許可執照影本。

二、醫療器材許可證影本。

三、醫療器材使用說明書。

四、宣導計畫書，包括包裝量改變之情形。

五、申請數量及計算依據。

第16條

符合第二條第四款第二目資格，申請捐贈醫療器材贈品者，其應檢附之文件、資料如下：

一、捐贈者說明文件：捐贈事由、受贈對象、捐贈品項及數量。

二、受贈者說明文件：受贈醫療器材之名稱及數量，並聲明不販售、轉讓或轉供他用。

三、醫療器材使用說明書、外盒或目錄。

第17條

第二條第四款第三目自然人，申請專供個人自用之醫療器材者，其應檢附之文件、資料如下：

一、申請人身分證明文件。

二、醫療器材使用說明書。

三、載有不販售、轉讓或轉供他用意旨之切結書。

四、國內、外就診醫療機構出具載有醫療器材名稱之診斷證明或處方。

前項申請，委託代理人辦理者，並應檢附代理人身分及委託證明文件。

第18條

第二條第五款維修業者申請輸入醫療器材者，其應檢附之文件、資料如下：

一、醫療器材商許可執照影本，其營業項目應包括維修。

二、載有委託者名稱或姓名、委託維修意旨及維修期間之證明文件。

三、醫療器材使用說明書。

四、其他中央主管機關指定之文件、資料。

第19條

第二條第六款醫療器材商申請醫療器材製造或輸入者，其應檢附之文件、資料如下：

一、醫療器材商許可執照影本：

（一）申請製造者：醫療器材製造業許可執照。

107

The documents and materials that must be attached are as follows:

1. A photocopy of the Medical Device Company Permit License.

2. A photocopy of the Medical Device License.

3. The medical device instructions for use.

4. The promotional plan, including details on changes to packaging quantity.

5. The quantity applied for and the basis for calculation.

Article 16

Applicants who meet the qualifications specified in Article 2, Paragraph 4, Subparagraph 2 and apply for the donation of medical devices as gifts must attach the following documents and materials:

1. Donor's explanation document: reason for donation, recipient, donated item(s), and quantity.

2. Recipient's explanation document: name and quantity of the medical device received, along with a declaration that they will not sell, transfer, or supply the item for other uses.

3. Medical device instructions for use, outer packaging, or catalog.

Article 17

Individual persons as described in Article 2, Paragraph 4, Subparagraph 3 applying for medical devices exclusively for personal use must attach the following documents and materials:

1. Applicant's identification document.

2. The medical device instructions for use.

3. A declaration stating the intent not to sell, transfer, or supply the product for other uses.

4. A medical certificate or prescription issued by a domestic or foreign medical institution listing the name of the medical device.

If an agent is entrusted to handle the application in the preceding paragraph, identification and proof of authorization for the agent must also be attached.

Article 18

For maintenance service providers as stated in Article 2, Paragraph 5, applying for the importation of medical devices, the following documents and materials must be attached:

1. A photocopy of the Medical Device Company Permit License, with a business scope that includes maintenance.

2. Documentary proof stating the name of the commissioning party, the purpose of maintenance, and the maintenance period.

3. The medical device instructions for use.

4. Other documents and materials as designated by the central competent authority.

Article 19

For medical device companies as specified in Article 2, Paragraph 6, applying for the manufacture or importation of medical devices, the following documents and materials must be attached:

1. A photocopy of the Medical Device Company Permit License:

Translated by RegDesk AI

(1) For applicants for manufacturing: the Medical Device Manufacturing Industry Permit License.

Translated by RegDesk AI

（二）申請輸入者：醫療器材販賣業許可執照。

二、醫療器材結構、規格、性能、用途、圖樣、製造品質資料、安全性與效能試驗報告、人體使用資料及風險利益評估報告。

三、製造廠符合醫療器材品質管理系統準則之文件。

四、申請數量及計算依據。

五、醫療器材使用說明書。

六、其他中央主管機關指定之文件、資料。

前項第二款及第三款文件、資料，得以國外政府核准製造銷售證明替代。

第20條

中央主管機關受理第六條第一項之申請，應審酌其申請事由、利益風險及數量計算方式，為准駁之決定，並得為附款。

第21條

依前條核准製造或輸入之醫療器材，應依下列規定標示：

一、本法第三十五條第一項第二款及第六款之用者：包裝上依中央主管機關核准函內容標示。

二、本法第三十五條第一項第三款專供試驗者：包裝上標示「臨床試驗用」字樣。

三、本法第三十五條第一項第四款專供樣品或贈品者：包裝上分別標示「樣品」或「贈品」字樣。

第22條

中央主管機關核准第二條第一款、第二款或第六款申請製造或輸入者，得通知申請人限期提交實際使用之安全或效能評估報告；屆期未提交，或提交之評估報告經審核認有安全或效能疑慮者，中央主管機關得廢止其核准。

第23條

依本辦法核准製造或輸入之醫療器材，其使用及處置，不得逾越或違反核准之目的、限制、方式、期限或其他相關內容。

第24條

依本辦法核准輸入之醫療器材，除專供個人自用者、受其器材使用目的或本質限制，或其他特殊情形經中央主管機關同意者外，申請人應於輸入原因消滅後一個月內退運出口，並將海關退運出口證明文件送中央主管機關備查。

第25條

本辦法自中華民國一百十年五月一日施行。

(2) Applicant for Import: Permit license for medical device dealers.

2. Documentation regarding the structure, specifications, performance, intended use, diagrams, manufacturing quality data, safety and efficacy test reports, clinical usage data, and risk-benefit assessment reports for the medical device.

3. Documentation demonstrating the manufacturer’s compliance with medical device quality management systems standards.

4. Quantity to be applied for and the basis of calculation.

5. Instructions for use for the medical device.

6. Other documents and data as designated by the central competent authority.

The documentation and data specified in Items 2 and 3 of the preceding paragraph may be substituted with proof of approval for manufacture and sale from foreign governmental authorities.

Article 20

Upon accepting applications as per Article 6, Paragraph 1, the central competent authority shall review the grounds for application, benefit-risk assessment, and method of quantity calculation to determine whether to approve or reject the application, and may attach additional conditions.

Article 21

Medical devices approved for manufacture or import in accordance with the preceding article shall be labeled as follows:

1. For users as prescribed in Article 35, Paragraph 1, Subparagraphs 2 and 6 of this Act: labeling shall be done on the packaging according to the contents of the approval letter from the central competent authority.

2. For those exclusively for testing purposes as prescribed in Article 35, Paragraph 1, Subparagraph 3 of this Act: packaging shall be labeled with the wording "For Clinical Trial Use".

3. For those exclusively for sample or gift purposes as prescribed in Article 35, Paragraph 1, Subparagraph 4 of this Act: packaging shall be labeled with the wording "Sample" or "Gift", as appropriate.

Article 22

Where the central competent authority approves an application for manufacture or import under Subparagraphs 1, 2, or 6 of Article 2, it may notify the applicant to submit a safety or efficacy assessment report based on actual use within a specified period. Failure to submit within the deadline, or submission of an assessment report deemed to present safety or efficacy concerns after review, may result in the revocation of the approval by the central competent authority.

Article 23

Medical devices approved for manufacture or import under these Regulations shall not be used or disposed of beyond or in violation of the approved purpose, restrictions, methods, period, or any other relevant content.

Article 24

Translated by RegDesk AI

For medical devices approved for import under these Regulations—except for those exclusively for individual personal use, subject to the intended use or intrinsic limitations of the device, or other special circumstances as approved by the central competent authority—the applicant shall, within one month after the reason for import ceases to exist, export the products and submit the customs export documentation to the central competent authority for record.

Article 25

These Regulations shall be implemented from May 1, 2021.

Translated by RegDesk AI

附表

項次	中文名稱	規定
一	OK繃	合計不超過六十個（片）。
二	液體OK繃	合計不超過四條（罐、瓶、支）。
三	棉棒	合計不超過二百支。
四	衛生套	合計不超過六十個。
五	衛生棉條	合計不超過一百二十個。
六	日拋隱形眼鏡	單一度數六十片，惟每人以單一品牌及二種不同度數為限。
七	矯正鏡片	合計不超過一副。
八	醫用口罩	合計不超過二百五十個（片）。

109

Annex Table

It... No.	Chinese Name	Regulation
1	Band-Aids	A total of no more than sixty (pieces).
2	Liquid Band-Aid	A total of no more than four (tubes, cans, bottles, units).
3	Cotton Swabs	A total of no more than two hundred sticks.
4	Condoms	A total of no more than sixty.
5	Tampons	A total of no more than one hundred and twenty.
6	Daily Disposable Contact Lenses	Sixty pieces per single prescription strength; limited to a single brand and two different prescription strengths per person.
7	Corrective Lenses	A total of no more than one pair.
8	Medical Face Masks	A total of no more than two hundred and fifty (pieces).

Translated by RegDesk AI

【醫療器材優良臨床試驗管理辦法】(110.04.09發布)

第一章　總則

第1條

本辦法依醫療器材管理法（以下簡稱本法）第三十七條第三項規定訂定之。

第2條

本辦法用詞，定義如下：

一、受試者：指參與臨床試驗而接受試驗用醫療器材或作為試驗對照之個人。

二、易受傷害群體：指因年齡、智能或身體（生理）狀況缺乏充分決定能力，或因所處環境、身分或社會經濟狀況而容易遭受不當影響、脅迫或無法以自由意願作決定者。

三、試驗主持人：指臨床試驗機構執行臨床試驗之負責人。

四、試驗委託者：指臨床試驗之發起及管理者。

五、受託研究機構：指接受試驗委託者委託，執行試驗委託者有關臨床試驗之全部或一部業務。

六、試驗偏離：指未依臨床試驗計畫書規範執行之偏差情形。

七、不良事件：指受試者參加臨床試驗所發生，與試驗用醫療器材間不以具有因果關係為必要之不良情事。

八、醫療器材不良反應：指與試驗用醫療器材有關之不良事件。

九、嚴重不良事件：指受試者發生下列情事之一：

（一）死亡。

（二）危及生命。

（三）暫時或永久性失能。

（四）受試者之胎兒或嬰兒先天性畸形。

（五）需住院或延長住院。

（六）其他可能導致永久性傷害之併發症。

十、嚴重醫療器材不良反應：指與試驗用醫療器材有關之嚴重不良事件。

第3條

執行臨床試驗，應遵行下列規定：

一、符合赫爾辛基宣言之倫理原則。

二、符合科學原則。

三、符合風險最小化原則，對受試者侵害最小，並確保風險與利益相平衡。

110

Regulations for Good Clinical Practice of Medical Devices (Promulgated 2021.04.09)

Chapter 1 General Provisions

Article 1

These Regulations are enacted in accordance with Article 37, Paragraph 3 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

The terminology used in these Regulations is defined as follows:

1. Subject: Refers to an individual who participates in a clinical trial and receives the investigational medical device or serves as a control in the trial.

2. Vulnerable Population: Refers to individuals who lack sufficient decision-making capacity due to age, intelligence, or physical (physiological) condition, or who are easily subject to undue influence or coercion, or unable to make decisions of their own free will due to their environment, status, or socio-economic conditions.

3. Principal Investigator: Refers to the person responsible for conducting the clinical trial at the clinical trial institution.

4. Sponsor: Refers to the initiator and manager of the clinical trial.

5. Contract Research Organization: Refers to an institution commissioned by the sponsor to execute all or part of the sponsor's business concerning clinical trials.

6. Protocol Deviation: Refers to deviations from the clinical trial protocol as specified.

7. Adverse Event: Refers to an unfavorable occurrence affecting a subject during participation in a clinical trial, which does not necessarily have a causal relationship with the investigational medical device.

8. Adverse Device Effect: Refers to an adverse event related to the investigational medical device.

9. Serious Adverse Event: Refers to the occurrence of any of the following conditions in a subject:

(1) Death.

(2) Life-threatening event.

(3) Temporary or permanent disability.

(4) Congenital anomaly in the subject's fetus or infant.

(5) Hospitalization or prolonged hospitalization.

(6) Other complications that may result in permanent injury.

10. Serious Adverse Device Effect: Refers to a serious adverse event related to the investigational medical device.

Article 3

When conducting a clinical trial, the following requirements shall be observed:

1. Compliance with the ethical principles of the Declaration of Helsinki.

2. Compliance with scientific principles.

3. Adherence to the principle of minimizing risk, ensuring minimal harm to subjects, and safeguarding a balance between risk and benefit.

Translated by RegDesk AI

四、經臨床試驗倫理審查委員會（以下簡稱審查會）核准。

五、徵求受試者同意。

六、保障受試者之自主權及隱私權。

第4條

試驗委託者應擬訂臨床試驗計畫，經審查會及中央主管機關核准後，始得執行。

試驗主持人及臨床試驗機構應依前項核准之計畫，執行臨床試驗。

第二章　試驗委託者

第5條

試驗委託者應訂定、執行及管理臨床試驗工作，並確保資料之完整性及受試者之權利、安全與福祉。

第6條

試驗委託者應完成試驗用醫療器材之下列臨床前研究，並以臨床前數據及臨床評估之結果，證明試驗設計之合理性：

一、產品設計。

二、安全性及功能性測試。

三、風險分析。

四、其他必要之臨床前研究。

第7條

試驗委託者應於中央主管機關公告指定之網頁，依第四條第一項核准後三十日內，登錄下列臨床試驗相關資料：

一、臨床試驗機構名稱。

二、試驗委託者名稱。

三、試驗主持人姓名。

四、臨床試驗名稱。

五、臨床試驗核准文號。

六、臨床試驗核准日期。

七、臨床試驗目的。

八、受試者納入、排除條件。

九、受試者人數。

十、試驗用醫療器材名稱。

十一、臨床試驗階段。

111

4. Approved by the Institutional Review Board (hereinafter referred to as the IRB).

5. Obtain the consent of the subjects.

6. Protect the autonomy and privacy rights of the subjects.

Article 4

The trial sponsor shall formulate a clinical trial protocol, which may only be implemented after approval by the IRB and the central competent authority.

The principal investigator and the clinical trial institution shall conduct the clinical trial in accordance with the protocol approved in the preceding paragraph.

Chapter 2 Sponsor

Article 5

The sponsor shall establish, implement, and manage clinical trial activities, and ensure the integrity of data as well as the rights, safety, and well-being of subjects.

Article 6

The sponsor shall complete the following preclinical studies for the investigational medical device, and, based on preclinical data and the results of clinical evaluations, demonstrate the rationality of the trial design:

1. Product design.

2. Safety and functionality testing.

3. Risk analysis.

4. Other necessary preclinical studies.

Article 7

Within thirty days after approval in accordance with Paragraph 1 of Article 4, the sponsor shall register the following clinical trial-related information on the webpage designated and announced by the central competent authority:

1. Name of the clinical trial institution.

2. Name of the sponsor.

3. Name of the principal investigator.

4. Name of the clinical trial.

5. Approval document number of the clinical trial.

6. Approval date of the clinical trial.

7. Purpose of the clinical trial.

8. Inclusion and exclusion criteria for subjects.

9. Number of subjects.

10. Name of the investigational medical device.

11. Phase of the clinical trial.

Translated by RegDesk AI

十二、其他必要之登錄事項。

臨床試驗計畫有修正時，試驗委託者應於核准修正後三十日內更新登錄資料。

臨床試驗執行期間，試驗委託者應於每年六月及十二月定期更新登錄資料。

第8條

試驗委託者應訂定主持人手冊、臨床試驗計畫書、受試者同意書、個案報告表、相關標準作業流程及其他相關規定。

第9條

試驗委託者因臨床試驗致受試者傷害、死亡或其他損失者，應負醫療照護、損害賠償或損失補償及其他依法應負之責任。

有下列情形之一者，試驗委託者免負前項損害賠償或損失補償責任：

一、受試者同意書已記載臨床試驗可能發生之不良反應、副作用或風險。

二、試驗委託者能證明已善盡醫療上必要之注意。

三、試驗委託者能證明無故意或過失。

臨床試驗由試驗主持人發起者，臨床試驗機構應適用前二項規定。

第10條

執行臨床試驗前，試驗委託者應與臨床試驗機構及試驗主持人就試驗之職責分工、相關費用及可能發生之傷害、死亡或其他損失處理原則，達成協議，並以書面定之。

第11條

試驗委託者與受託研究機構間之職責分工，應以書面訂定協議。試驗委託者應對臨床試驗數據品質及完整性，負最終責任。

第12條

試驗委託者規劃跨臨床試驗機構之臨床試驗時，應就各臨床試驗機構之主持人，指派其中一人為總主持人，並協調總主持人及各主持人間之職責分工後，以書面定之。

第13條

試驗委託者應備妥試驗用醫療器材，該器材並應標示有「臨床試驗專用」之文字。

前項器材之研製，應符合醫療器材品質管理系統準則之規定。

112

12. Other necessary registration items.

In the event of any amendments to the clinical trial protocol, the trial sponsor shall update the registration information within thirty days after the approval of the amendment.

During the execution period of the clinical trial, the trial sponsor shall update the registration information regularly every June and December.

Article 8

The trial sponsor shall formulate the Investigator's Brochure, Clinical Trial Protocol, Informed Consent Form, Case Report Form, related Standard Operating Procedures, and other relevant regulations.

Article 9

In the event that a clinical trial causes injury, death, or other loss to a subject, the trial sponsor shall be responsible for medical care, compensation for damages or loss, and any other responsibilities required by law.

The trial sponsor shall be exempt from the liability for compensation for damages or loss as mentioned in the preceding paragraph if any of the following circumstances apply:

1. The informed consent form signed by the subject has stated the possible adverse reactions, side effects, or risks of the clinical trial.

2. The trial sponsor can prove that necessary medical care and attention have been exercised.

3. The trial sponsor can prove there was neither intent nor negligence.

If the clinical trial is initiated by the principal investigator, the clinical trial institution shall apply the preceding two paragraphs.

Article 10

Before conducting a clinical trial, the trial sponsor shall reach an agreement, in writing, with the clinical trial institution and the principal investigator regarding the division of trial responsibilities, related expenses, and principles for handling possible injuries, deaths, or other losses.

Article 11

The division of responsibilities between the trial sponsor and the contracted research organization shall be established by written agreement. The trial sponsor shall bear ultimate responsibility for the quality and integrity of clinical trial data.

Article 12

When the trial sponsor plans a clinical trial involving multiple clinical trial institutions, among the principal investigators of each clinical trial institution, one shall be designated as the overall principal investigator. The division of responsibilities among the overall principal investigator and each principal investigator shall be coordinated and set in writing.

Article 13

The trial sponsor shall prepare the investigational medical device, which shall be labeled with the wording "For Clinical Trial Use Only."

The development and manufacture of the aforementioned device shall comply with the regulatory requirements for medical device quality management systems.

Translated by RegDesk AI

第14條

審查會及中央主管機關依第四條第一項規定核准臨床試驗計畫前，試驗委託者不得提供試驗用醫療器材予臨床試驗機構及試驗主持人。

第15條

試驗委託者應製作並保存試驗用醫療器材之文件紀錄；其內容應包括試驗用醫療器材之生產日期、產品批號及運送、接收、儲存、配置、回收與銷燬之情形。

第16條

試驗委託者應將下列資訊，通知臨床試驗機構及試驗主持人，並作出相應處理：

一、影響臨床試驗安全性、合理性及其他影響受試者權益之重大資訊。

二、醫療器材有瑕疵導致不良反應之虞者。

三、其他與臨床試驗有關之重要資訊。

有前項各款情形之一，必要時，試驗委託者應修正試驗計畫書、主持人手冊、受試者同意書及相關規定，並報經審查會核准。

第17條

試驗委託者應監測下列事項：

一、試驗相關人員與實驗室、儀器或其他相關設備之適當、安全及正確性。

二、臨床試驗機構與試驗主持人對臨床試驗計畫書核定內容、相關法規及本辦法規定之遵行。

三、收案進度及受試者同意書之簽署。

四、下列個案報告表之登錄及其他與試驗相關紀錄之正確性與完整性：

（一）封面頁／登入頁、頁首或頁尾／電子個案報告表識別碼、個案報告表項目。

（二）退出試驗、未作檢驗、檢查或追蹤。

（三）不良事件或其他特殊反應及其通報。

五、試驗用醫療器材之供給、使用、維護、運輸、接收、儲存、處理及回收之妥當性。

六、臨床試驗相關儀器設備接受定期維護及校正。

七、試驗主持人與試驗相關人員已收到最新版本之臨床試驗相關文件。

試驗委託者得就前項監測，指派外部專業人員（以下簡稱監測者）執行。

第18條

監測者進行前條監測，應向試驗委託者提出書面報告；其內容如下：

Article 14

Prior to approval of the clinical trial protocol in accordance with Article 4, Paragraph 1 by the Review Board and the central competent authority, the trial sponsor shall not provide the investigational medical device to the clinical trial institution or the principal investigator.

Article 15

The trial sponsor shall produce and retain documentation records of the investigational medical device; the contents shall include the production date, product batch number, and the conditions of shipping, receiving, storage, allocation, retrieval, and destruction of the investigational medical device.

Article 16

The trial sponsor shall notify the clinical trial institution and principal investigator of the following information and take appropriate action:

1. Major information that affects the safety, rationale of the clinical trial, or other significant matters related to the rights and interests of the subjects.

2. Incidents where the medical device is suspected of defects that may lead to adverse reactions.

3. Other important information related to the clinical trial.

When any circumstances described in the preceding paragraph occur, if necessary, the trial sponsor shall amend the trial protocol, investigator's brochure, subject consent form, and related regulations, and submit them for approval to the Review Board.

Article 17

The trial sponsor shall monitor the following matters:

1. The appropriateness, safety, and accuracy of personnel involved in the trial, laboratories, instruments, or other relevant equipment.

2. Compliance by the clinical trial institution and principal investigator with the approved contents of the clinical trial protocol, applicable regulations, and the provisions of these Regulations.

3. Progress of subject enrollment and the signing of subject consent forms.

4. The accuracy and completeness of the following case report forms and other trial-related records:

(1) Cover page/login page, header or footer/electronic case report form identification code, and case report form items.

(2) Subject withdrawal, missed inspections, tests, or follow-up.

(3) Adverse events or other special reactions and their reporting.

5. The appropriateness of the supply, use, maintenance, transportation, receipt, storage, handling, and retrieval of the investigational medical device.

6. The acceptance of regular maintenance and calibration for clinical trial-related instruments and equipment.

7. The principal investigator and relevant personnel have received the latest versions of trial-related documents.

The trial sponsor may assign external professionals (hereinafter referred to as "monitors") to conduct the monitoring described in the preceding paragraph.

Article 18

Translated by RegDesk AI

The monitor, when conducting monitoring in accordance with the preceding article, shall submit a written report to the trial sponsor; the contents shall include:

Translated by RegDesk AI

一、監測日期及地點。
二、監測者姓名。
三、試驗主持人姓名。
四、臨床試驗進度。
五、偏離或缺失。
六、當次監測之評估結果。
七、建議改進之措施。

第19條

試驗委託者應自行或委託臨床試驗團隊及監測者以外之機構或人員，就臨床試驗是否遵行臨床試驗計畫書、標準作業、本辦法、相關法規及研究倫理之事項，進行稽核。

第20條

前條稽核，應依下列規定辦理：
一、試驗委託者依臨床試驗之重要性、受試者人數、試驗種類、複雜性及受試者風險訂定稽核計畫及標準作業規定。
二、依前款計畫及標準作業規定執行。
三、稽核者之觀察、發現及結果，應以書面記錄之。

第21條

試驗委託者發現下列情事之一者，應即中止或終止臨床試驗，並依第六十四條辦理：
一、未依規定經審查會通過或中央主管機關核可，自行變更臨床試驗內容。
二、顯有影響受試者權益、安全之事實。
三、不良事件發生數或嚴重度顯有異常。
四、有足以影響臨床試驗成果評估之事件。
五、臨床試驗未完成前，有具體事實證明並無實益、風險高於潛在利益，或顯有實益致不利於對照組。

第22條

試驗委託者應妥善保存臨床試驗之所有文件及更新版本；其保存期間，至臨床試驗完成後或該醫療器材依本法規定登錄或取得許可證後至少三年，二者以期間較後者為準。

第23條

試驗委託者規劃之臨床試驗使用電子資料處理系統時，應執行下列事項：

114

1. Monitoring date and location.

2. Name of the monitor.

3. Name of the principal investigator.

4. Progress of the clinical trial.

5. Deviations or deficiencies.

6. Evaluation results of the current monitoring.

7. Suggested corrective actions.

Article 19

The trial sponsor shall, on its own or by commissioning an institution or personnel other than the clinical trial team and monitors, conduct audits to ensure that the clinical trial is conducted in accordance with the clinical trial protocol, standard operating procedures, these Regulations, relevant laws and regulations, and research ethics.

Article 20

The audit in the preceding article shall be conducted in accordance with the following provisions:

1. The trial sponsor shall establish an audit plan and standard operating procedures according to the importance of the clinical trial, the number of subjects, type of trial, complexity, and risk to subjects.

2. Execution shall be in accordance with the plan and standard operating procedures mentioned in the preceding subparagraph.

3. Observations, findings, and results of the audit shall be recorded in writing.

Article 21

If the trial sponsor discovers any of the following circumstances, the clinical trial shall be suspended or terminated immediately and handled in accordance with Article 64:

1. Unauthorized changes to the clinical trial content without approval from the review committee or the central competent authority as required.

2. Facts that clearly affect the rights and safety of subjects.

3. Abnormal number or severity of adverse events.

4. Events sufficient to affect the assessment of clinical trial outcomes.

5. Before completion of the clinical trial, concrete evidence shows no actual benefit, that the risk outweighs potential benefits, or obvious benefit results in disadvantage to the control group.

Article 22

The trial sponsor shall properly retain all documents and updated versions related to the clinical trial; the retention period shall be at least three years after completion of the clinical trial or after the medical device is registered or obtains a license in accordance with these laws and regulations, whichever period is longer.

Article 23

When a trial sponsor plans to use an electronic data processing system for a clinical trial, the following actions shall be carried out:

Translated by RegDesk AI

一、訂定系統規格需求。
二、確認系統符合前款規格需求。
三、確認輸入數據之精確度、完整性、可信度及一致性。
四、確認系統輸出報告之正確性。
五、確認數據修改皆有記錄，且不得將原始及歷次修正數據刪除，應保留稽核路徑、資料路徑及編輯路徑。
六、維持防護系統，防止未經授權者存取數據。
七、保存授權使用系統人員之名單及使用期間與權限之紀錄。
八、確認個案報告表有試驗主持人或其授權人員之簽章。
九、定期備份系統資料。
十、訓練系統使用者正確使用。

第24條

臨床試驗由試驗主持人發起者，本辦法對試驗委託者之規定，於試驗主持人，適用之。

第三章　臨床試驗機構及試驗主持人

第25條

臨床試驗機構執行臨床試驗前，應依試驗用醫療器材之特性，就其人力、空間、設施及設備進行評估，並作成評估報告書。

第26條

臨床試驗機構執行臨床試驗，應經該機構審查會，或依法委託其他機構設立之審查會或共同約定之審查會審查通過後，始得為之。

第27條

試驗主持人，應具備下列資格及條件：
一、領有執業執照，並從事臨床醫療五年以上之醫師。但依本法第三十七條第一項但書公告無顯著風險之臨床試驗，得以領有中央主管機關核發之師類醫事人員專門職業證書，且實際從事五年以上相關專業工作者為之。
二、最近六年曾受臨床試驗相關訓練三十小時，且至少包括醫療器材臨床試驗及醫學倫理各九小時之相關課程。
三、試驗用醫療器材必要操作能力，經取得證明文件。

醫事人員曾受懲戒處分或因違反臨床試驗相關法規規定，受停業一個月以上或廢止執業執照處分者，不得擔任前項主持人。

115

1. Establish system specification requirements.

2. Confirm that the system meets the specification requirements set forth in the preceding subparagraph.

3. Verify the accuracy, completeness, reliability, and consistency of input data.

4. Verify the correctness of system output reports.

5. Ensure that all data modifications are recorded and that neither the original nor any revised data may be deleted; audit trails, data paths, and edit paths must be retained.

6. Maintain protective systems to prevent unauthorized persons from accessing data.

7. Retain a list of personnel authorized to use the system and keep records of their periods of use and access rights.

8. Ensure that case report forms bear the signature or seal of the principal investigator or authorized personnel.

9. Regularly back up system data.

10. Train system users in proper utilization.

Article 24

If a clinical trial is initiated by the principal investigator, the provisions of these Regulations applicable to a sponsor shall also apply to the principal investigator.

Chapter 3 Clinical Trial Institutions and Principal Investigators

Article 25

Before conducting a clinical trial, a clinical trial institution shall, in accordance with the characteristics of the investigational medical device, evaluate its manpower, space, facilities, and equipment, and produce an evaluation report.

Article 26

A clinical trial institution may conduct a clinical trial only after it has been reviewed and approved by the institution's review board, or by the review board of another institution commissioned according to law, or by a jointly agreed-upon review board.

Article 27

The principal investigator must possess the following qualifications and conditions:

1. Hold a medical practice license and have engaged in clinical medical practice for more than five years. However, for clinical trials announced as posing no significant risk under the proviso of Article 37, Paragraph 1 of this Act, a person holding a professional license for a relevant medical profession issued by the central competent authority and having at least five years of relevant professional experience may serve as principal investigator.

2. Within the past six years, have received at least 30 hours of training related to clinical trials, including at least nine hours of courses related to clinical trials of medical devices and at least nine hours related to medical ethics.

3. Have the necessary operational skills for the investigational medical device, as evidenced by relevant certification documents.

Translated by RegDesk AI

Medical personnel who have been subject to disciplinary action, or who have had their practice license suspended for one month or more, or revoked due to violations of clinical trial-related regulations, may not serve as principal investigator as mentioned in the preceding paragraph.

Translated by RegDesk AI

第28條

試驗主持人應嚴格遵守臨床試驗計畫之內容。但有緊急情況須執行必要處置者，不在此限。

前項但書，試驗主持人應於處置完成後七日內以書面敘明理由，報審查會及試驗委託者備查。

第29條

臨床試驗數據應準確、完整、即時記載於個案報告表；其有更改時，應載明更改日期及更改人之姓名，並保留原記載內容。試驗主持人應確保其正確性，並簽名。

第30條

臨床試驗機構及試驗主持人，應妥善保存臨床試驗相關紀錄、文件及資料；其保存期間，至試驗完成後至少三年。但其他法規規定之保存期間逾三年者，從其規定。

第31條

臨床試驗機構及試驗主持人，應妥善保存試驗用醫療器材，並確保其僅用於經核准之臨床試驗。

第32條

試驗主持人或其指定之人員，應於試驗前充分告知受試者臨床試驗資訊、同意書內容及已知或可能發生之不良事件，經其瞭解後簽名，並載明日期。

第33條

試驗主持人於發生不良事件或發現試驗用醫療器材有瑕疵時，應予記錄。

第34條

臨床試驗機構及試驗主持人，於受試者參加試驗及後續追蹤期間，發生不良事件時，應予充分醫療照護。

第35條

臨床試驗機構或試驗主持人發現臨床試驗之風險超過預期利益，或有其他足以影響試驗適當性之情事者，應即中止或終止臨床試驗，並通報審查會及試驗委託者。

第36條

中央主管機關得對臨床試驗機構及試驗主持人進行查核，並要求提供臨床試驗有關之資料。

116

Article 28

The principal investigator shall strictly comply with the contents of the clinical trial protocol. However, in cases of emergency where it is necessary to take appropriate actions, this requirement does not apply.

In the situation outlined in the preceding proviso, the principal investigator shall, within seven days after the completion of the action, provide a written explanation stating the reasons to the Institutional Review Board (IRB) and the trial sponsor for recordkeeping.

Article 29

Clinical trial data shall be accurately, completely, and promptly recorded in the case report forms. If there are any changes, the amendment date and the name of the person making the amendment shall be indicated, and the original information shall be retained. The principal investigator shall ensure its accuracy and sign it.

Article 30

The clinical trial institution and the principal investigator shall properly retain records, documents, and data related to the clinical trial; the retention period shall be at least three years after the completion of the trial. However, if other regulations stipulate a retention period exceeding three years, such provisions shall prevail.

Article 31

The clinical trial institution and the principal investigator shall properly store the investigational medical device and ensure it is only used for the approved clinical trial.

Article 32

Before the trial, the principal investigator or their designated personnel shall fully inform the subject of information regarding the clinical trial, the content of the informed consent form, and any known or potential adverse events. After the subject has understood the information, they shall sign and date the form.

Article 33

When an adverse event occurs or when a defect in the investigational medical device is discovered, the principal investigator shall record it.

Article 34

During the period when a subject is participating in the trial and during subsequent follow-up, if an adverse event occurs, the clinical trial institution and the principal investigator shall provide adequate medical care.

Article 35

If the clinical trial institution or the principal investigator discovers that the risks of the clinical trial exceed its anticipated benefits or becomes aware of any other circumstances that may affect the appropriateness of the trial, they shall immediately suspend or terminate the clinical trial and notify the Institutional Review Board and the trial sponsor.

Article 36

The central competent authority may conduct inspections of the clinical trial institution and the principal investigator, and may require the provision of relevant clinical trial information.

Translated by RegDesk AI

臨床試驗機構及試驗主持人對前項之查核與要求，不得妨礙、規避或拒絕。

第四章　臨床試驗倫理審查委員會

第37條

審查會所為臨床試驗之審查，其範圍包括下列項目：

一、臨床試驗計畫之申請、修正、終止及中止後繼續執行。

二、定期期中報告。

三、試驗偏離報告。

四、嚴重不良事件報告。

五、結案報告。

六、研究人員利益衝突事項之揭露。

七、其他臨床試驗相關之重要事項。

審查會對執行中之臨床試驗，每年應至少查核一次。

第38條

審查會於臨床試驗計畫之審查，應注意下列事項：

一、臨床試驗設計與執行符合最小化風險原則，對受試者侵害最小，並確保風險與利益相平衡。

二、執行方式及內容符合科學原則。

三、受試者之條件及召募方式。

四、受試者之醫療照護、損害賠償或損失補償及其他救濟機制。

五、受試者之隱私保護。

六、受試者同意書內容及告知程序。

七、易受傷害群體之保護。

八、保障受試者安全之必要管理措施。

第39條

第三十七條審查，其審查決定應以書面為之，並載明下列事項：

一、試驗計畫名稱。

二、臨床試驗計畫書、受試者同意書、個案報告表及其他臨床試驗相關資料之版本編號與制定日期。

三、臨床試驗機構、試驗主持人及試驗委託者。

四、審查結果及其理由。

五、審查決議作成日期。

117

Clinical trial institutions and principal investigators must not obstruct, evade, or refuse the audits and requests mentioned in the preceding paragraph.

Chapter IV Ethics Committee for Clinical Trials

Article 37

The scope of the ethics committee's review of clinical trials includes the following items:

1. Applications, modifications, termination, and continued execution after suspension of clinical trial protocols.

2. Regular interim reports.

3. Protocol deviation reports.

4. Serious adverse event reports.

5. Final reports.

6. Disclosure of matters relating to conflicts of interest of the investigators.

7. Other important matters related to clinical trials.

The ethics committee shall audit ongoing clinical trials at least once per year.

Article 38

When reviewing clinical trial protocols, the ethics committee shall pay attention to the following matters:

1. That the design and execution of the clinical trial adhere to the principle of minimizing risks, ensuring the lowest possible harm to subjects, and maintaining a balance between risks and benefits.

2. That the methods and content of execution conform to scientific principles.

3. The eligibility criteria for subjects and methods of recruitment.

4. The medical care, compensation for injury or loss, and other relief mechanisms for subjects.

5. The protection of subject privacy.

6. The content of the informed consent form and the information process.

7. Protection of vulnerable populations.

8. Necessary management measures to ensure the safety of subjects.

Article 39

For reviews conducted pursuant to Article 37, the review decisions shall be made in writing and shall specify the following details:

1. Title of the trial protocol.

2. Version number and creation date of the clinical trial protocol, subject informed consent form, case report form, and other related clinical trial documents.

3. Clinical trial institution, principal investigator, and sponsor.

4. Review results and the reasons thereof.

5. Date the review resolution was made.

Translated by RegDesk AI

第40條

審查會應置委員五人以上，包括法律專家及其他社會公正人士；臨床試驗機構以外人士應達五分之二以上；任一性別委員，不得低於委員總數三分之一。

第41條

審查會委員有下列情形之一者，應即迴避：

一、為試驗主持人、協同主持人或試驗委託者。

二、與試驗主持人有配偶、四親等內之血親或三親等內之姻親或曾有此關係。

三、與試驗委託者有聘僱關係。

四、其他經審查會認有利益迴避之必要。

第42條

審查會委員未親自參與審查會之審查及討論，不得參與決議。

第43條

審查會委員及其他參與審查事務者，就其職務上知悉之資訊，無正當理由，不得洩漏。

第44條

審查會之人員名單及會議紀錄，應予公開。

第45條

審查會為第三十七條之審查或查核時，發現有下列情事之一者，得命試驗主持人或試驗委託者限期改善、中止或終止臨床試驗：

一、未依規定經審查會或中央主管機關核准，自行變更臨床試驗內容。

二、顯有影響受試者權益、安全之事實。

三、不良事件發生數或嚴重度顯有異常。

四、有事實足認臨床試驗已無必要。

五、發生其他影響試驗之風險及利益評估情事。

第46條

臨床試驗完成後，有下列情形之一者，審查會應進行調查，並通報臨床試驗機構及中央主管機關：

一、違反法規或計畫內容。

二、嚴重晚發性不良事件。

三、嚴重影響受試者權益。

118

Article 40

The Review Board shall have no fewer than five members, including legal experts and other socially impartial individuals; members who are not affiliated with the clinical trial institution shall account for no less than two-fifths of the total; members of either gender shall not be less than one-third of the total number of committee members.

Article 41

Any of the following circumstances shall require a member of the Review Board to recuse themselves immediately:

1. Serving as the principal investigator, co-investigator, or sponsor of the trial.

2. Having a spousal relationship, blood relationship within the fourth degree, or affinity within the third degree with the principal investigator, or having previously held such relationship.

3. Having an employment relationship with the sponsor.

4. Other situations where the Review Board deems recusal necessary due to a conflict of interest.

Article 42

A member of the Review Board who does not personally participate in the review and discussion at the Review Board meeting shall not participate in any resolution.

Article 43

Members of the Review Board and others involved in review matters must not disclose any information learned in the course of their duties without legitimate reason.

Article 44

The roster of the Review Board and the meeting minutes shall be made public.

Article 45

When conducting reviews or inspections as described in Article 37, if the Review Board discovers any of the following circumstances, it may order the principal investigator or sponsor to make improvements within a specified period, or to suspend or terminate the clinical trial:

1. Any unauthorized changes to the clinical trial content without approval from the Review Board or the central competent authority as required by regulations.

2. There is clear evidence affecting the rights or safety of the subjects.

3. The number or severity of adverse events is exceptionally abnormal.

4. There are sufficient facts to determine that the clinical trial is no longer necessary.

5. Other situations affecting the assessment of the risks and benefits of the trial.

Article 46

After the completion of a clinical trial, if any of the following conditions arise, the Review Board shall conduct an investigation and notify the clinical trial institution and the central competent authority:

1. Violation of laws or the content of the protocol.

2. Severe late-onset adverse events.

3. Serious impact on the rights of the subjects.

Translated by RegDesk AI

第47條

審查會應將試驗計畫書、會議紀錄、查核紀錄及其他相關文件、資料，保存至試驗完成後至少三年。

第48條

審查會對於中央主管機關之查核，不得規避、妨礙或拒絕。

第五章　受試者同意書

第49條

受試者同意書，應由受試者、受試者之法定代理人、輔助人或監護人及試驗主持人或協同主持人簽名，並載明日期。

前項受試者同意書副本，應交予受試者。

第50條

受試者應以有意思能力之成年人為限。但對特定人口群或特殊疾病罹患者健康權益之試驗顯有助益者，不在此限。

前項但書之受試者為限制行為能力人或受輔助宣告之人者，應得其本人，及法定代理人或輔助人之同意；為無行為能力者，應得其法定代理人或監護人之同意。其屬人體研究法第十二條第三項之情形者，並得依該條規定辦理。

前項無行為能力人，試驗主持人應於其得以理解之範圍內，告知臨床試驗相關資訊。

受試者行為能力及受輔助宣告之情事有變更者，其臨床試驗之同意，應重新為之。

第51條

本法第三十七條第二項所稱情況緊急者，指符合下列各款情形，且於臨床試驗計畫中載明臨床試驗得於取得受試者、法定代理人、輔助人或監護人書面同意前執行者，免先取得受試者之同意：

一、受試者有緊急且危及生命之情況。

二、預期無法以現有治療方法達到足夠之臨床效益。

三、使用試驗用醫療器材可能緩解危及生命之風險。

四、使用試驗用醫療器材之可能利益超過其預期風險。

五、受試者無意思能力且無法及時通知法定代理人、輔助人或監護人。

前項情形，於能取得受試者、法定代理人、輔助人或監護人書面同意時，應即補正；其未補正者，不得使用受試者相關資料。

119

Article 47

The Institutional Review Board (IRB) shall retain the trial protocol, meeting minutes, audit records, and other related documents and materials for at least three years after the completion of the trial.

Article 48

The IRB shall not evade, obstruct, or refuse audits conducted by the central competent authority.

Chapter V Informed Consent Form

Article 49

The informed consent form shall be signed and dated by the subject, the subject's legal representative, assistant, or guardian, and by the principal investigator or co-investigator.

A copy of the informed consent form referenced in the preceding paragraph shall be provided to the subject.

Article 50

Subjects shall be limited to adults with capacity to make decisions. However, this restriction does not apply if the trial is clearly beneficial to the health rights and interests of specific populations or individuals suffering from particular diseases.

For subjects under the exception clause in the preceding paragraph who have limited capacity to act or are subject to an assistant declaration, consent shall be obtained from both the individual and their legal representative or assistant; for individuals with no capacity to act, consent shall be obtained from their legal representative or guardian. In circumstances as stipulated in Paragraph 3, Article 12 of the Human Research Act, such matters may also be handled in accordance with the provisions of that Article.

For subjects with no capacity to act as stated in the preceding paragraph, the principal investigator shall, as far as they are able to understand, inform them of relevant clinical trial information.

If there is any change in the subject’s capacity to act or in the status regarding the assistant declaration, consent for participation in the clinical trial shall be obtained anew.

Article 51

The term "emergency circumstances" referred to in Paragraph 2, Article 37 of this Act means the following conditions are met, and the clinical trial protocol specifies that, prior to obtaining written consent from the subject, legal representative, assistant, or guardian, the clinical trial may proceed without first obtaining the subject's consent:

1. The subject is in an emergency and life-threatening situation.

2. It is expected that sufficient clinical benefit cannot be achieved by existing treatment methods.

3. The use of the investigational medical device may alleviate life-threatening risks.

4. The potential benefits of the investigational medical device outweigh its anticipated risks.

5. The subject lacks capacity to make decisions and it is not possible to inform the legal representative, assistant, or guardian in a timely manner.

Under circumstances mentioned in the preceding paragraph, written consent from the subject, legal representative, assistant, or guardian shall be obtained as soon as possible; if such consent is not obtained, the subject’s related data may not be used.

Translated by RegDesk AI

第52條

前條受試者、法定代理人、輔助人或監護人得隨時撤回同意。

臨床試驗機構對不同意參與臨床試驗者或經前項撤回同意之受試者，應執行常規治療，不得減損其正當醫療權益。

第53條

受試者、法定代理人、輔助人或監護人，均無法閱讀受試者同意書及其他提供予受試者之所有書面資料時，應由見證人在場參與有關受試者同意之討論。

見證人應閱讀前項同意書及資料，並見證試驗主持人或其指定之人員已將其內容向受試者、法定代理人、輔助人或監護人為完整之說明。

見證人應確定受試者、法定代理人、輔助人或監護人已充分了解試驗之內容及權利與義務，及其決定係出於自由意願。

經完成前三項程序，同意參與試驗者，受試者、法定代理人、輔助人或監護人及見證人，應於受試者同意書親筆簽名，並載明日期。除見證人外，得以指印代替簽名。

試驗相關人員，不得為見證人。

第54條

受試者同意書，應載明下列各款事項：

一、試驗委託者及試驗機構名稱。

二、試驗主持人之姓名、職稱及聯絡資訊。

三、試驗目的及方法。

四、可預期風險及副作用。

五、預期試驗效果。

六、其他可能之治療方式及說明。

七、受試者得隨時撤回同意。

八、試驗有關之損失補償、損害賠償或保險機制。

九、臨床試驗不得向受試者收取任何費用。

十、受試者個人資料依法應予保密。但必要時，試驗委託者、審查會及中央主管機關得隨時檢視。

十一、受試者生物檢體、個人資料或其衍生物之保存及再利用。

十二、試驗用醫療器材於國內登錄或取得醫療器材許可證之情形。

第55條

受試者同意書之修正對受試者權益有影響者，應事先取得受試者、法定代

Article 52

The subjects, legal representatives, assistants, or guardians referred to in the preceding Article may withdraw their consent at any time.

The clinical trial institution shall provide standard treatment for those who do not consent to participate in the clinical trial or for subjects whose consent has been withdrawn as stated in the preceding paragraph, and shall not diminish their legitimate medical rights and interests.

Article 53

When the subject, legal representative, assistant, or guardian is unable to read the informed consent form or any other written materials provided to the subject, a witness shall be present to participate in the discussions regarding the subject's consent.

The witness shall read the aforementioned consent form and materials, and witness that the principal investigator or designated personnel has provided a complete explanation of their contents to the subject, legal representative, assistant, or guardian.

The witness shall ensure that the subject, legal representative, assistant, or guardian fully understands the content of the trial, their rights and obligations, and that the decision is made of their own free will.

Upon completion of the procedures specified in the preceding three paragraphs, those who consent to participate in the trial—the subject, legal representative, assistant, or guardian, as well as the witness—shall affix their personal signature and date to the informed consent form. Except for the witness, a fingerprint may be used in lieu of a signature.

Personnel related to the trial shall not act as witnesses.

Article 54

The informed consent form shall specify the following items:

1. Name of the trial sponsor and trial institution.

2. Name, title, and contact information of the principal investigator.

3. Purpose and methodology of the trial.

4. Foreseeable risks and side effects.

5. Expected effects of the trial.

6. Other possible treatment options and their explanations.

7. The subject may withdraw consent at any time.

8. Compensation for loss, compensation for damage, or insurance mechanisms related to the trial.

9. No fees of any kind shall be charged to the subjects for the clinical trial.

10. The subject’s personal data shall be kept confidential in accordance with the law. However, the sponsor, review board, and central competent authority may review them at any time if necessary.

11. Storage and reuse of the subject’s biological specimens, personal data, or their derivatives.

12. Registration or medical device license status of the trial medical device in the country.

Article 55

If amendments to the informed consent form affect the rights and interests of the subject, the prior consent of the subject, legal repre...

Translated by RegDesk AI

理人、輔助人或監護人同意，並簽名及載明日期後，始得依修正後之受試者同意書執行。

第56條

試驗委託者、試驗主持人或其他相關人員不得以脅迫、金錢或其他不正當方式，誘使受試者參與臨床試驗。

試驗委託者、試驗主持人或其他相關人員給予受試者交通費、營養費或其他相當之給付者，應載明於受試者同意書。

第57條

試驗委託者或臨床試驗機構，不得向受試者收取臨床試驗有關之任何費用。

第六章　臨床試驗申請、中止、終止及結案

第58條

臨床試驗機構或試驗委託者申請醫療器材臨床試驗，應填具申請書，並檢附下列文件、資料：

一、醫療器材商許可執照。

二、臨床試驗計畫書及其中文摘要。

三、受試者同意書。

四、個案報告表。

五、試驗主持人及臨床試驗機構之資格證明。

六、第二十五條之評估報告書。

七、臨床試驗可能之損失補償、損害賠償措施及相關文件。

八、試驗主持人手冊。

九、試驗用醫療器材臨床前資料及說明書。

臨床試驗由臨床試驗機構提出申請者，得免檢附前項第一款文件。

第59條

臨床試驗計畫書，應載明下列事項：

一、臨床試驗名稱。

二、試驗委託者姓名及地址。

三、臨床試驗機構名稱。

四、試驗主持人及協同主持人姓名、職稱及聯絡資訊。

五、試驗目的。

六、試驗設計。

121

The legal representative, assistant, or guardian must provide consent, sign, and specify the date before implementation based on the revised informed consent form of the subject.

Article 56

The trial sponsor, principal investigator, or other related personnel must not use coercion, money, or other improper means to induce subjects to participate in a clinical trial.

If the trial sponsor, principal investigator, or other related personnel provide subjects with transportation expenses, nutritional expenses, or other equivalent payments, such provision must be specified in the subject's informed consent form.

Article 57

The trial sponsor or clinical trial institution must not charge subjects any costs related to the clinical trial.

Chapter 6: Clinical Trial Application, Suspension, Termination, and Closure

Article 58

When a clinical trial institution or trial sponsor applies for a medical device clinical trial, they must complete an application form and submit the following documents and materials:

1. Medical device business license.

2. Clinical trial protocol and its Chinese summary.

3. Subject informed consent form.

4. Case report form.

5. Qualifications of the principal investigator and clinical trial institution.

6. Evaluation report as specified in Article 25.

7. Compensation for possible losses, indemnification measures for damages, and relevant documents relating to the clinical trial.

8. Investigator’s brochure.

9. Preclinical data and instructions for the clinical trial medical device.

If the clinical trial is applied for by a clinical trial institution, the document specified in Item 1 of the preceding paragraph may be exempted from submission.

Article 59

The clinical trial protocol must specify the following items:

1. Title of the clinical trial.

2. Name and address of the trial sponsor.

3. Name of the clinical trial institution.

4. Names, titles, and contact information of the principal and co-investigators.

5. Purpose of the trial.

6. Trial design.

Translated by RegDesk AI

七、試驗用醫療器材基本資訊。

八、受試者條件、招募方法及數目。

九、知情同意程序。

十、數據處理程序。

十一、統計考量。

十二、不良事件、醫療器材不良反應及醫療器材有瑕疵之情形。

十三、偏離臨床試驗計畫之記錄、通報及分析程序。

十四、臨床試驗中止、終止之條件及後續措施。

第60條

試驗主持人手冊，應載明下列事項：

一、試驗用醫療器材之基本資訊。

二、試驗用醫療器材之臨床前測試資料。

三、試驗用醫療器材已知之臨床試驗資料。

四、試驗用醫療器材之風險管理。

第61條

試驗委託者於臨床試驗計畫有修正時，應填具申請書，並檢附下列文件、資料，向中央主管機關申請：

一、中央主管機關歷次核准之公文影本。

二、修正前後之文件、資料。

三、修正前後對照表。

前項修正，經中央主管機關核准後，始得執行。

第62條

執行臨床試驗期間，試驗委託者、試驗主持人及臨床試驗機構應依中央主管機關之通知，提出試驗情形報告。

第63條

試驗委託者於試驗完成或終止後，應作成結案報告，並報中央主管機關備查。

第64條

依第二十一條、第三十五條、第四十五條或依本法第三十九條規定中止或終止試驗時，試驗委託者應即通知臨床試驗機構、試驗主持人、審查會及中央主管機關。

臨床試驗由試驗主持人發起者，前項通知，由臨床試驗機構為之。

122

7. Basic information of the investigational medical device.

8. Subject eligibility criteria, recruitment methods, and number of subjects.

9. Informed consent process.

10. Data processing procedures.

11. Statistical considerations.

12. Adverse events, adverse reactions of the medical device, and conditions pertaining to defective medical devices.

13. Procedures for recording, reporting, and analyzing protocol deviations of the clinical trial.

14. Conditions for suspension or termination of the clinical trial and subsequent actions.

Article 60

The Investigator's Brochure shall specify the following:

1. Basic information of the investigational medical device.

2. Preclinical test data of the investigational medical device.

3. Known clinical trial data of the investigational medical device.

4. Risk management related to the investigational medical device.

Article 61

When the sponsor makes amendments to the clinical trial protocol, an application form shall be completed and the following documents and materials shall be submitted to the central competent authority for approval:

1. Copies of official documents approved by the central competent authority in all previous instances.

2. Documents and materials before and after the amendment.

3. Comparative table of the pre- and post-amendment contents.

Amendments under the preceding paragraph shall only be implemented after approval by the central competent authority.

Article 62

During the conduct of the clinical trial, the sponsor, principal investigator, and clinical trial institution shall submit reports on the trial status in accordance with the notification from the central competent authority.

Article 63

Upon completion or termination of the trial, the sponsor shall prepare a closing report and submit it for record to the central competent authority.

Article 64

Where a trial is suspended or terminated pursuant to Articles 21, 35, 45, or Article 39 of this Act, the sponsor shall immediately notify the clinical trial institution, principal investigator, review board, and the central competent authority.

If the clinical trial is initiated by the principal investigator, the above-mentioned notification shall be made by the clinical trial institution.

Translated by RegDesk AI

第65條

已中止之臨床試驗，應經審查會及中央主管機關核准後，始得繼續執行。

第66條

臨床試驗結案報告經同意核備或同意結案前，試驗委託者、試驗機構或試驗主持人不得對外發表成果或為宣傳。

前項成果發表及宣傳之限制，試驗委託者、試驗機構或試驗主持人不得藉採訪或報導規避之。

第67條

臨床試驗屬本法第三十七條第一項但書無顯著風險者，不適用第五十八條及第六十一條至第六十四條規定；第四條及第六十五條有關向中央主管機關申請核准之規定，亦不適用之。

第七章　不良事件之對應

第68條

臨床試驗發生嚴重不良事件，或有導致嚴重醫療器材不良反應之虞者，試驗主持人應即通知臨床試驗機構、試驗委託者及審查會，並提出詳細書面報告。

第69條

除本法第三十八條規定外，試驗委託者獲知醫療器材有瑕疵可能導致嚴重醫療器材不良反應者，試驗委託者應通報中央主管機關。

前項通報，應於得知事實後七日內為之，並於十五日內檢具詳細調查資料報中央主管機關。

第70條

第十二條之試驗委託者，應將各臨床試驗機構通報之嚴重不良事件，以書面通知所有試驗主持人，並確認試驗主持人均已向其所屬之審查會通報。

第八章　附則

第71條

本辦法施行前，試驗委託者或臨床試驗機構已依醫療器材臨床試驗相關法令規定核准之臨床試驗，依原規定辦理。

第72條

本辦法自中華民國一百十年五月一日施行。

Article 65

A clinical trial that has been suspended may only resume after obtaining approval from both the Institutional Review Board (IRB) and the central competent authority.

Article 66

Before the clinical trial's final report is approved and filed, or before approval of trial closure, the sponsor, clinical trial institution, or principal investigator shall not disclose results to the public or engage in publicity activities.

The restriction on publication and publicity under the preceding paragraph may not be circumvented by the sponsor, clinical trial institution, or principal investigator through interviews or news coverage.

Article 67

Clinical trials that, pursuant to the proviso to Article 37, Paragraph 1 of this Act, pose no significant risk are not subject to the provisions of Articles 58 and 61 through 64; nor are the application and approval requirements of Article 4 and Article 65 pertaining to applying to the central competent authority applicable.

Chapter 7 Correspondence to Adverse Events

Article 68

If a serious adverse event occurs in a clinical trial, or if there is a risk of causing a serious adverse reaction to medical devices, the principal investigator shall immediately notify the clinical trial institution, the sponsor, and the IRB, and submit a detailed written report.

Article 69

Except as stipulated in Article 38 of this Act, if the sponsor becomes aware of a defect in the medical device that may cause a serious adverse reaction to medical devices, the sponsor shall notify the central competent authority.

The notification in the preceding paragraph shall be made within seven days of becoming aware of the fact, and detailed investigation data shall be submitted to the central competent authority within fifteen days.

Article 70

Sponsors as set out in Article 12 shall notify all principal investigators in writing of any serious adverse events reported by clinical trial institutions, and shall confirm that all principal investigators have reported such events to their respective IRBs.

Chapter 8 Supplementary Provisions

Article 71

For clinical trials approved by the sponsor or clinical trial institution in accordance with relevant medical device clinical trial regulations before the enforcement of these Regulations, the original provisions shall apply.

Article 72

These Regulations shall be implemented from May 1, 2021.

Translated by RegDesk AI

【醫療器材安全監視管理辦法】(110.04.28發布)

第1條

本辦法依醫療器材管理法（以下簡稱本法）第四十七條第三項規定訂定之。

第2條

本辦法適用範圍如下：

一、中央主管機關公告指定一定種類或品項之醫療器材。

二、其他中央主管機關公告指定之特定醫療器材。

第3條

前條醫療器材，以下列方式執行安全監視：

一、蒐集、調查、統計及分析醫療器材國內、外使用人數、不良事件之項目與發生數，及有關其使用之文獻或相關佐證資料。

二、醫療器材許可證所有人或登錄者，應依中央主管機關指定之特定安全問題，擬訂計畫，就特定使用者定期追蹤、蒐集、調查、統計及分析該特定安全之風險。

第4條

前條安全監視之期間，自發證日、登錄日、公告日或指定日起三年；必要時，中央主管機關得於安全監視計畫執行前、執行中或執行期滿後延長之。

第5條

醫療器材許可證所有人或登錄者，執行第三條第一款安全監視，應依中央主管機關公告指定之內容、格式，訂定計畫書執行；計畫書，應由醫療器材許可證所有人或登錄者留存備查。

醫療器材許可證所有人或登錄者，執行第三條第二款安全監視，應就其監視對象、範圍、內容、方式、監視期間、報告繳交期限及其他應執行事項，擬訂計畫書報中央主管機關審核通過後，始得為之；計畫書有變更者，亦同。

前二項計畫書，應載明之項目如附件一。

第6條

醫療器材許可證所有人或登錄者，執行第三條第一款之安全監視，應蒐集國內、外醫療器材之安全資料，除依醫療器材嚴重不良事件通報辦法之規定為通報外，應依附件二或中央主管機關公告指定之內容、格式，至中央主管機關指定之網路系統，登載定期安全性報告。

前項報告，自發證日、登錄日或安全監視公告日起，每半年填具當期蒐集

124

[Medical Device Safety Surveillance Management Regulations] (Promulgated 2021.04.28)

Article 1

These Regulations are enacted pursuant to Article 47, Paragraph 3 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

The scope of application of these Regulations is as follows:

1. Medical devices of certain categories or items as publicly announced and designated by the central competent authority.

2. Other specific medical devices as publicly announced and designated by the central competent authority.

Article 3

The safety surveillance for medical devices under the preceding Article shall be conducted in the following manners:

1. Collection, investigation, statistical analysis of the number of users domestically and abroad, the types and occurrences of adverse events relating to the medical device, as well as relevant literature or supporting information related to its use.

2. The medical device license holder or registrant shall, in accordance with specific safety concerns designated by the central competent authority, formulate a plan to regularly follow up, collect, investigate, and statistically analyze users with respect to the risks of such specific safety concerns.

Article 4

The period for the safety surveillance prescribed in the preceding Article shall be three years from the date of certificate issuance, registration, public announcement, or designation; if necessary, the central competent authority may extend this period before, during, or after execution of the safety surveillance plan.

Article 5

When conducting safety surveillance under Subparagraph 1, Article 3, the medical device license holder or registrant shall prepare and implement a plan in accordance with the contents and formats announced and designated by the central competent authority; such plan shall be retained by the license holder or registrant for reference.

When conducting safety surveillance under Subparagraph 2, Article 3, the medical device license holder or registrant shall prepare a plan specifying the subjects, scope, content, methods, surveillance period, deadlines for report submission, and other items to be executed, and may only proceed after approval by the central competent authority; the same shall apply to any amendments to the plan.

The items to be specified in the plans mentioned in the preceding two paragraphs are listed in Attachment 1.

Article 6

Translated by RegDesk AI

When conducting safety surveillance under Subparagraph 1, Article 3, the medical device license holder or registrant shall collect safety information on medical devices both domestically and internationally; in addition to reporting in accordance with the Regulations on Reporting Serious Adverse Events of Medical Devices, periodic safety reports shall be recorded via the online system designated by the central competent authority, in accordance with Attachment 2 or the contents and formats announced and designated by the central competent authority.

Periodic reports shall be prepared every six months from the date of certificate issuance, registration, or public announcement of the safety surveillance.

Translated by RegDesk AI

所得資料，於該期截止日後三十日內登載；必要時，中央主管機關得要求其於指定期日登載。

第一項所有人或登錄者，應於計畫書所定安全監視期間屆滿後六十日內，依附件三內容、格式，填具安全監視期間所得之安全資料，至中央主管機關指定之網路系統，登載總結報告。

第7條

第三條第二款醫療器材許可證所有人或登錄者，應於監視期間蒐集國內、外醫療器材之安全資料，除依醫療器材嚴重不良事件通報辦法之規定為通報外，應依中央主管機關核定之分期、期間及報告登載期限，至中央主管機關指定之網路系統，登載安全性報告；必要時，中央主管機關得要求其於指定期日登載。

未能依前條或前項規定，至中央主管機關指定網路系統登載者，得先以紙本方式為之，並依中央主管機關指定之期限補正登載。

第8條

醫療器材許可證所有人或登錄者，蒐集、鑑別、檢索、保存及處理前二條所定資料時，應建立管理程序。

第9條

醫療器材許可證所有人或登錄者，應保存第六條及第七條資料至監視期間屆滿後五年。

第10條

醫療器材許可證所有人或登錄者，經依本法第十六條規定停業，其安全監視計畫未能執行完竣者，應自停業日起六十日內，就其已執行部分，至中央主管機關指定之網路系統，登載已執行部分之定期安全性報告；其嗣後復業者，安全監視計畫應接續予以完成。

未能依前項規定，至中央主管機關指定網路系統登載者，得先以紙本方式為之，並依中央主管機關指定之期限補正登載。

第11條

醫療器材許可證經中央主管機關核准移轉登記，其監視尚未完成或第九條之保存期間未屆滿者，原醫療器材許可證所有人，應將安全監視資料交付予受讓人，並由受讓人依本辦法規定續行監視或保存。

第12條

醫療器材許可證所有人或登錄者，執行安全監視，其計畫書內容涉及臨床

125

The obtained data shall be published within thirty days after the end date of the respective period; when necessary, the central competent authority may require its publication by a specified date.

The owner or registrant referred to in Paragraph 1 shall, within sixty days after the expiration of the safety surveillance period specified in the protocol, complete a summary report of the safety data obtained during the surveillance period in accordance with the content and format stipulated in Attachment 3, and upload it to the internet system designated by the central competent authority.

Article 7

The medical device license holder or registrant under Subparagraph 2, Article 3, shall collect safety data on domestic and overseas medical devices during the surveillance period. In addition to reporting according to the Regulations for Medical Device Serious Adverse Event Notification, the safety report shall be uploaded to the internet system designated by the central competent authority according to the phases, periods, and report uploading deadlines approved by the central competent authority; when necessary, the central competent authority may require its upload by a specified date.

If unable to upload in accordance with the preceding Article or the preceding paragraph to the internet system designated by the central competent authority, submission may first be made in paper form, and the upload shall be corrected within the deadline specified by the central competent authority.

Article 8

The medical device license holder or registrant, when collecting, identifying, retrieving, preserving, and processing data as prescribed in the preceding two Articles, shall establish management procedures.

Article 9

The medical device license holder or registrant shall retain the data stipulated in Articles 6 and 7 for five years after the expiration of the surveillance period.

Article 10

Where a medical device license holder or registrant is ordered to cease operations under Article 16 of this Act and the safety surveillance plan cannot be completed, the license holder or registrant shall, within sixty days from the date of cessation, upload a periodic safety report of the portions completed to the internet system designated by the central competent authority; if business operations are resumed afterward, the safety surveillance plan shall be continued and completed.

If unable to upload in accordance with the preceding paragraph to the internet system designated by the central competent authority, submission may first be made in paper form, and the upload shall be corrected within the deadline specified by the central competent authority.

Article 11

Where a medical device license is transferred with approval from the central competent authority and the surveillance has not been completed or the retention period in Article 9 has not expired, the original license holder shall deliver the safety surveillance data to the transferee, and the transferee shall continue surveillance or retention in accordance with these Regulations.

Article 12

The medical device license holder or registrant, when conducting safety surveillance and the contents of the protocol involve clinical...

Translated by RegDesk AI

試驗或人體研究者，應依本法或人體研究法規定辦理。

第13條

醫療器材商及醫事機構為執行醫療器材安全監視，有蒐集、處理或利用個人資料之必要時，應依醫療法、個人資料保護法及其相關法規規定辦理。

第14條

本辦法所定報告，應以正體中文登載，不得自行刪減項目或以「詳見附件」方式為之；登載之附件，非正體中文或英文者，應另登載正體中文或英文譯本。

第15條

本辦法自中華民國一百十年五月一日施行。

126

Trials or human studies shall be conducted in accordance with this Act or the relevant provisions of the Human Research Act.

Article 13

When medical device firms and medical institutions need to collect, process, or use personal data to carry out medical device safety surveillance, they shall proceed in accordance with the Medical Care Act, the Personal Data Protection Act, and related regulations.

Article 14

Reports stipulated in these Regulations shall be written in Traditional Chinese and shall not have sections arbitrarily omitted or replaced by stating "see attachment"; attachments provided that are not in Traditional Chinese or English shall be accompanied by a translation in Traditional Chinese or English.

Article 15

These Regulations shall be enforced from May 1, 2021.

Translated by RegDesk AI

【醫療器材嚴重不良事件通報辦法】(110.04.28發布)

第1條

本辦法依醫療器材管理法第四十八條第二項規定訂定之。

第2條

本辦法所稱醫療器材嚴重不良事件，指因使用醫療器材致生下列各款情形之一或有致生之虞者：

一、死亡。

二、危及生命。

三、永久性殘疾。

四、胎嬰兒先天性畸形。

五、需住院或延長住院。

六、其他可能導致永久性傷害之併發症。

第3條

醫療器材商為醫療器材許可證所有人或登錄者及醫事機構，發現國內醫療器材嚴重不良事件時，應至中央主管機關指定之網路系統，將事件資料通報至中央主管機關，或其委託之機構、法人或團體。

前項以外醫療器材商發現國內醫療器材嚴重不良事件時，得通知醫療器材許可證所有人或登錄者。

第一項不良事件之通報，必要時，得先以口頭方式為之，並應依第五條或第六條所定期限，補正前項網路通報。

未能依第一項及前項規定辦理網路通報者，應填具通報表（如附表），以紙本、傳真、書信或電子郵件之方式完成通報。

第一項及前二項通報，其內容未完備者，中央主管機關或其委託機構、法人或團體，得指定期限通知其補正。

第4條

醫療器材許可證所有人或登錄者及醫事機構為前條之通報，其內容應至少包括下列事項：

一、通報廠商或機構之名稱、地址、聯絡方式及通報人姓名。

二、嚴重不良事件發生日期及發現日期。

三、醫療器材中文品名及許可證字號或登錄字號。

四、醫療器材之型號或規格及批號。

五、醫療器材直接供應來源及流向；通報者為不良事件發生之最終使用機構，無須通報產品流向。

127

[Regulations for Reporting Serious Adverse Events of Medical Devices] (Promulgated on 2021.04.28)

Article 1

These Regulations are enacted pursuant to Paragraph 2, Article 48 of the Medical Devices Act.

Article 2

The term "serious adverse event of medical devices" as used in these Regulations refers to any of the following circumstances resulting from the use of a medical device, or where there is concern that such circumstances may occur:

1. Death.

2. Life-threatening situations.

3. Permanent disability.

4. Congenital malformation of a fetus or neonate.

5. Hospitalization or prolongation of existing hospitalization.

6. Other complications that may result in permanent injury.

Article 3

When medical device enterprises that are license holders or registrants and medical institutions discover a domestic serious adverse event of a medical device, they shall, via the Internet system designated by the central competent authority, report the event data to the central competent authority or to an institution, juridical person, or organization commissioned by the authority.

Medical device enterprises other than those mentioned in the preceding paragraph, upon discovering a domestic serious adverse event of a medical device, may notify the license holder or registrant of the device.

Where necessary, the report of the adverse event specified in Paragraph 1 may be made orally at first, but a supplementary online report shall be completed within the time limit prescribed in Article 5 or Article 6.

If unable to complete the online report in accordance with Paragraph 1 and the preceding paragraph, a notification form (as per the attached table) shall be filled out, and notification shall be completed by paper, fax, letter, or email.

If the content of the notifications in Paragraphs 1 and the preceding two paragraphs is incomplete, the central competent authority or its commissioned institution, juridical person, or organization may notify the notifier to make corrections within a specified period.

Article 4

For the notifications made by the license holder or registrant and medical institutions in accordance with the preceding Article, the content shall at least include the following items:

1. Name, address, contact information of the reporting enterprise or institution, and the name of the reporter.

2. Date of occurrence and date of discovery of the serious adverse event.

3. Chinese product name of the medical device and license number or registration number.

4. Model or specification and batch number of the medical device.

5. Direct source and flow of the medical device; if the reporter is the terminal user institution where the adverse event occurred, notification of product flow is not required.

Translated by RegDesk AI

六、發生嚴重不良事件之醫療器材現況。

七、不良事件之類別及結果。

八、不良事件發生之描述。

前項第八款描述，應包括下列事項：

一、發生不良反應之部位、症狀及嚴重程度。

二、產品問題。

三、可能導致嚴重傷害之原因及過程。

四、病人後續處置。

第5條

醫事機構應依下列期限為第三條之通報，並副知醫療器材許可證所有人或登錄者：

一、第二條第一款及第二款：自發現之日起七日內。

二、第二條第三款至第六款：自發現之日起十五日內。

醫事機構辦理前項通報，得要求醫療器材商提供通報表相關資料；醫療器材商應予配合。

第6條

醫療器材許可證所有人或登錄者為第三條之通報，應於發現第二條事件之日起十五日內完成。

第7條

醫療器材許可證所有人或登錄者完成前條通報後，應主動調查，評估矯正、預防措施採行之必要性及矯正、預防措施之執行內容。

前項調查及評估結果，醫療器材許可證所有人或登錄者，應通報中央主管機關或第三條第一項受委託機構、法人或團體；其通報方式，準用第三條規定；有採矯正、預防措施必要者，並應將該措施，通知使用該醫療器材之醫事機構。

第8條

醫療器材許可證所有人或登錄者及醫事機構，應保存醫療器材嚴重不良事件通報內容，及前條調查、評估與矯正、預防措施之文件、資料，其保存期間至少五年；五年內，其許可證有移轉者，受讓人應於該期間內續行保存。

第9條

中央主管機關或其委託機構、法人或團體，得要求醫療器材商及醫事機構，提供醫療器材嚴重不良事件之病人或醫療器材相關文件、資料；被要求者不

128

6. Current status of the medical device involved in the serious adverse event.

7. Category and outcome of the adverse event.

8. Description of the occurrence of the adverse event.

The description in Subparagraph 8 of the preceding paragraph shall include the following items:

(1) The site, symptoms, and severity of the adverse reaction.

(2) Product issues.

(3) Causes and processes that could lead to serious injury.

(4) Follow-up handling of the patient.

Article 5

Medical institutions shall report as required under Article 3 within the following time limits, and notify the holder of the medical device permit license or registrant:

(1) For Subparagraphs 1 and 2 of Article 2: within seven days from the date of discovery.

(2) For Subparagraphs 3 to 6 of Article 2: within fifteen days from the date of discovery.

When a medical institution processes the notification in the preceding paragraph, it may require the medical device company to provide relevant information for the reporting form; the medical device company shall cooperate accordingly.

Article 6

The holder of the medical device permit license or registrant shall complete the report under Article 3 within fifteen days from the date of discovery of an event under Article 2.

Article 7

After completing the report under the preceding article, the holder of the medical device permit license or registrant shall proactively investigate and assess the necessity of corrective and preventive actions and the content of their implementation.

The results of the investigation and assessment in the preceding paragraph shall be reported by the holder of the medical device permit license or registrant to the central competent authority or to the commissioned organization, legal person, or group specified in Paragraph 1 of Article 3; the reporting method shall be handled mutatis mutandis in accordance with the provisions of Article 3. If corrective or preventive actions are necessary, such measures shall be notified to the medical institutions using the medical device.

Article 8

The holder of the medical device permit license or registrant and medical institutions shall retain the content of serious adverse event reports for medical devices, as well as documents and data related to the investigation, assessment, corrective, and preventive actions set out in the preceding article, for no less than five years; if the permit license is transferred within five years, the transferee shall continue to retain the documents within this period.

Article 9

The central competent authority or its commissioned organization, legal person, or group may require medical device companies and medical institutions to provide documents and data related to the patient or the medical device involved in the serious adverse event; the party so required shall not

Translated by RegDesk AI

得規避、妨礙或拒絕。

第10條

醫療器材商及醫事機構，依本辦法蒐集、處理或利用個人資料，應依個人資料保護法及其相關法規規定辦理。

第 11 條

本辦法自中華民國一百十年五月一日施行。

129

May be circumvented, obstructed, or refused.

Article 10

Medical device traders and healthcare institutions, when collecting, processing, or using personal data in accordance with these Regulations, shall comply with the Personal Data Protection Act and related regulations.

Article 11

These Regulations shall enter into force on May 1, 2021.

Translated by RegDesk AI

【輸入醫療器材邊境抽查檢驗辦法】(111.07.08修正)

第一章　總則

第1條

本辦法依醫療器材管理法（以下簡稱本法）第五十二條第二項規定訂定之。

第2條

本辦法用詞，定義如下：

一、查驗：指對輸入醫療器材於輸入許可前，以逐批或抽批方式所為之查核、檢驗。

二、查核：指由查驗人員依法執行品目、包裝外觀、標示或其他項目之檢查、核對。

三、檢驗：指於實驗室進行感官、化學、生物或物理性之檢查、化驗。

四、查驗機關：指辦理輸入醫療器材查驗之中央主管機關或其委任之機關或委託之機關（構）。

五、報驗義務人：指醫療器材之輸入業者。

第二章　輸入醫療器材查驗申請

第3條

中央主管機關應實施邊境查驗之醫療器材品項，規定如附表一。

第4條

依本法第五十二條第一項規定，申請輸入前條醫療器材者，應由報驗義務人於輸入前十五日起，填具查驗申請書，並檢附下列文件、資料，向輸入港埠所在地之查驗機關提出：

一、醫療器材許可證、登錄證明或專案輸入核准文件影本。

二、進口報單影本。

三、其他經中央主管機關指定之文件、資料。

前項申請由代理人為之者，應另檢附代理人證明文件及委託書。但報驗義務人檢具長期代理委託契約，並向查驗機關報備者，不在此限。

第一項申請，中央主管機關得要求報驗義務人以電子方式為之。

第一項申請文件、資料有不備，其得補正者，查驗機關應通知報驗義務人於二十日內補正；屆期未補正者，予以駁回。

130

Regulations for Border Inspection and Testing of Imported Medical Devices(Amended 2022.07.08)

Chapter I General Provisions

Article 1

These Regulations are enacted pursuant to Article 52, Paragraph 2 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

The terms used in these Regulations are defined as follows:

1. Inspection and testing: Refers to the examination or testing, by batch or by sampling, of imported medical devices before the issuance of import permits.

2. Examination: Refers to the examination and verification, in accordance with the law by inspection personnel, of items including product name, packaging appearance, labeling, or other aspects.

3. Testing: Refers to sensory, chemical, biological, or physical examination and analysis conducted in laboratories.

4. Inspection Authority: Refers to the central competent authority responsible for the inspection and testing of imported medical devices, or any body or institution so commissioned or delegated.

5. Declarant: Refers to the importer of the medical device.

Chapter II Application for Inspection and Testing of Imported Medical Devices

Article 3

The types of medical devices subject to border inspection by the central competent authority are specified in Appendix 1.

Article 4

Pursuant to Article 52, Paragraph 1 of the Act, applicants seeking to import the medical devices referred to in the preceding article shall, within fifteen days prior to importation, complete and submit an application for inspection and attach the following documents and information to the inspection authority at the port of entry:

1. A copy of the medical device permit, registration certificate, or approval documents for special import.

2. A copy of the import declaration form.

3. Other documents and information as specified by the central competent authority.

Where the application referred to in the preceding paragraph is made by an agent, a power of attorney and proof of agency must also be submitted. However, if the declarant provides a long-term agency agreement and has reported it to the inspection authority, this requirement is exempted.

The central competent authority may require the application mentioned in Paragraph 1 to be submitted electronically by the declarant.

If the documents or information submitted in accordance with Paragraph 1 are incomplete but may be supplemented, the inspection authority shall notify the declarant to make corrections within twenty days; failure to do so within the time limit will result in rejection of the application.

Translated by RegDesk AI

第5條

輸入醫療器材有下列情形之一者，免依前條規定申請查驗：

一、依本法第三十五條第一項第四款規定，核准專供樣品或個人自用。

二、國內製造醫療器材輸出，經中央主管機關核准運返國內。

三、經互惠免驗優待之輸出國政府發給檢驗合格證明。

四、為因應國家緊急情況或促進公益，經中央主管機關核准。

第三章　查驗程序

第6條

查驗機關實施查驗，就下列方式擇一或合併為之：

一、逐批查驗：對各批次輸入醫療器材，均予查驗。

二、抽批查驗：對申請查驗之醫療器材，依下列抽驗率執行抽批；經抽中者，予以查驗：

（一）一般抽批查驗：抽驗率為百分之二至百分之十。

（二）加強抽批查驗：抽驗率為百分之二十至百分之五十。

三、現場查核：於醫療器材存置處所執行查核。

輸入之醫療器材，其查核項目、檢驗項目及檢驗方法，規定如附表二。

第7條

輸入醫療器材有下列情形之一者，採逐批查驗：

一、報驗義務人首次輸入之前三批同品目、同商標（牌名）及同產地之醫療器材。

二、報驗義務人前一批輸入之同品目、同商標（牌名）及同產地之醫療器材，經加強抽批查驗結果不符合規定。

三、查驗機關認有逐批查驗之必要。

逐批查驗未完成前，同一報驗義務人再申請查驗者，仍依逐批查驗方式執行。

第8條

輸入醫療器材有下列情形之一者，採加強抽批查驗：

一、報驗義務人前一批輸入為同品目、同商標（牌名）及同產地者，經一般抽批查驗結果不符合規定。

二、查驗機關認有加強抽批查驗之必要。

第9條

輸入醫療器材有下列情形之一者，採一般抽批查驗：

Article 131

Article 5

Imported medical devices meeting any of the following circumstances are exempt from the application for inspection as stipulated in the preceding article:

1. Approved as exclusively for sample or for personal use in accordance with Article 35, Paragraph 1, Subparagraph 4 of this Act.

2. Domestically manufactured medical devices that were exported and are re-imported with approval from the central competent authority.

3. Certificate of inspection compliance issued by the government of an export country that is granted reciprocal inspection exemption privileges.

4. Approved by the central competent authority in response to national emergencies or for the promotion of public welfare.

Chapter 3 Inspection Procedures

Article 6

The inspection authority may carry out inspection by selecting one or a combination of the following methods:

1. Batch-by-batch inspection: Each batch of imported medical devices is inspected.

2. Random sampling inspection: For medical devices subject to inspection application, samples are taken for inspection at the following sampling rates; those selected are inspected:

(1) General random sampling inspection: Sampling rate is 2% to 10%.

(2) Enhanced random sampling inspection: Sampling rate is 20% to 50%.

3. On-site verification: Verification is conducted at the storage location of the medical devices.

The inspection items, test items, and test methods for imported medical devices are stipulated as in Appendix Table 2.

Article 7

For imported medical devices with any of the following circumstances, batch-by-batch inspection shall be adopted:

1. For an applicant's first three batches of imported medical devices of the same product type, same trademark (brand name), and same country of origin.

2. For the previous batch of the same product type, same trademark (brand name), and same country of origin imported by the applicant, if the result of enhanced random sampling inspection did not meet requirements.

3. When the inspection authority deems batch-by-batch inspection necessary.

Before completion of batch-by-batch inspection, if the same applicant applies for another inspection, batch-by-batch inspection shall still be implemented.

Article 8

For imported medical devices with any of the following circumstances, enhanced random sampling inspection shall be adopted:

1. The previous batch of the same product type, same trademark (brand name), and same country of origin imported by the applicant did not meet requirements as a result of general random sampling inspection.

Translated by RegDesk AI

2. When the inspection authority deems enhanced random sampling inspection necessary.

Article 9

For imported medical devices with any of the following circumstances, general random sampling inspection shall be adopted:

Translated by RegDesk AI

一、依第七條第一項第一款逐批查驗後，皆符合規定。

二、依第七條第一項第二款逐批查驗或前條加強抽批查驗，連續五批皆符合規定，且連續輸入五批符合規定之累計數量，達前一批查驗結果不符合規定之三倍量。

第10條

查驗機關辦理查驗所需樣品，以無償方式取得；其數量，以足供檢驗所需者為限。

查驗機關抽取樣品後，應開具取樣憑單予報驗義務人。

第11條

查驗之取樣，應於醫療器材存置處所實施。

醫療器材由整裝貨櫃裝運者，應於海關指定之集中查驗區或經查驗機關認可之特定區域實施；其單一貨櫃抽樣耗時長久或有其他困難者，得要求拆櫃進倉為之。

前項查驗，報驗義務人應予配合，且不得指定樣品。

第12條

輸入醫療器材之檢驗，應依取樣先後順序為之。但依第十五條申請複驗者，原檢驗之實驗室應提前檢驗。

第13條

查驗機關對於在貨櫃場取樣困難、檢驗時間超過五日、容易腐敗、變質或其安全功效穩定性不足之醫療器材，得於報驗義務人書立切結書表明負保管責任後，簽發輸入醫療器材具結先行放行通知書，供其辦理先行通關，並存置於特定地點。

前項具結先行放行之醫療器材，報驗義務人切結之存置地點與實際不符，或於核發輸入許可通知前，擅自啟用、移動或販售者，查驗機關應暫停受理該報驗義務人具結先行放行申請一年。

第14條

輸入醫療器材經查驗合格者，查驗機關應核發輸入許可，並通知報驗義務人；報驗義務人亦得向查驗機關申請核發書面之許可通知書。

報驗義務人應自收受許可通知之次日起十五日內，憑取樣憑單領取餘存樣品；屆期未領取或樣品性質不適合久存者，查驗機關得逕行處置。

第15條

輸入醫療器材查驗不合格者，查驗機關應核發輸入不合格之通知予報驗義

132

1. In accordance with Article 7, Paragraph 1, Subparagraph 1, batch-by-batch inspections have all complied with the regulations.

2. In accordance with Article 7, Paragraph 1, Subparagraph 2, batch-by-batch inspections or strengthened random inspections under the preceding article, if five consecutive batches comply with the regulations, and the cumulative quantity of the five consecutive compliant batches reaches three times the quantity of the previous non-compliant inspection result.

Article 10

The inspection authority shall obtain the necessary samples for inspection at no cost; the quantity shall be limited to that required for the inspection.

After sampling, the inspection authority shall issue a sampling receipt to the person responsible for declaration.

Article 11

Sampling for inspection shall be conducted at the storage location of the medical devices.

For medical devices shipped in sealed containers, sampling shall be carried out in the centralized inspection area designated by customs or in a specific area approved by the inspection authority; if sampling a single container is time-consuming or faces other difficulties, disassembly of the container for warehousing may be required.

For the inspection in the preceding paragraph, the person responsible for declaration shall cooperate and shall not designate samples.

Article 12

Inspection of imported medical devices shall follow the order of sampling. However, if a re-inspection is applied for in accordance with Article 15, the original testing laboratory shall prioritize the inspection.

Article 13

For cases where sampling at the container yard is difficult, testing requires more than five days, the medical device is prone to spoilage or deterioration, or its safety and efficacy stability is insufficient, the inspection authority may issue a Notification of Conditional Advance Release for Imported Medical Devices, allowing advance customs clearance and storage at a specified location, provided that the person responsible for declaration submits a written undertaking assuming custody responsibility.

If the storage location stated in the undertaking for the conditionally advanced released medical devices does not match the actual location, or if the devices are activated, moved, or sold without authorization before the import permit notification is issued, the inspection authority shall suspend acceptance of such person’s applications for conditional advance release for one year.

Article 14

For imported medical devices that pass inspection, the inspection authority shall issue an import permit and notify the person responsible for declaration; the person responsible for declaration may also apply to the inspection authority for a written permit notification.

The person responsible for declaration shall, within fifteen days starting from the day following receipt of the permit notification, claim the remaining samples with the sampling receipt; if not claimed within the period, or if the nature of the samples is not suitable for long-term storage, the inspection authority may dispose of them directly.

Article 15

Translated by RegDesk AI

If imported medical devices fail inspection, the inspection authority shall issue a notice of nonconformity to the person responsible for declaration.

Translated by RegDesk AI

務人。

報驗義務人於收受前項通知之次日起十五日內，得向查驗機關申請複驗，以一次為限。

複驗時，由查驗機關就原抽取餘存樣品為之；餘存之樣品不足供複驗者，得依第十一條規定，再行辦理抽樣。

第一項查驗不合格之醫療器材，其餘存樣品，除法律另有規定外，於申請複驗之期限屆至後，應予銷燬。

第16條

輸入之醫療器材經查驗不合格者，除法律另有規定外，應由報驗義務人辦理退運或銷燬。

查驗不合格之醫療器材，經具結先行放行者，查驗機關應通知報驗義務人依前項規定辦理，並副知直轄市、縣（市）主管機關。

第四章　規費

第17條

依本辦法辦理查驗，報驗義務人應繳納下列行政規費：

一、審查費。

二、現場查核費。

三、通知書費。

四、電腦傳送訊息更正費。

五、檢驗費。

前項各款收費數額，規定如附表三。

第五章　附則

第18條

查驗人員依本辦法執行查驗業務時，應出示有關執行業務之證明文件或顯示足以辨識其身分之標誌。

第19條

本辦法自中華民國一百十年五月一日施行。

本辦法修正條文，自發布日施行。

133

Obligee.

The inspection applicant may, within fifteen days from the day following receipt of the aforementioned notice, apply to the inspection authority for a re-inspection; this is limited to one time only.

During re-inspection, the inspection authority shall use the remaining original sample for re-inspection; if the remaining sample is insufficient for re-inspection, re-sampling may be conducted in accordance with Article 11.

For medical devices that failed the initial inspection, except as otherwise provided by law, any remaining samples shall be destroyed after the deadline for applying for re-inspection has passed.

Article 16

If imported medical devices fail inspection, except as otherwise provided by law, the inspection applicant shall handle re-export or destruction.

For medical devices that have failed inspection but have been released with an affidavit, the inspection authority shall notify the inspection applicant to handle the matter according to the preceding paragraph, and shall also notify the competent authorities of the municipality or county (city) for their reference.

Chapter IV: Fees

Article 17

For inspections handled in accordance with these Regulations, the inspection applicant shall pay the following administrative fees:

1. Review fee.

2. On-site inspection fee.

3. Notification letter fee.

4. Computerized message correction fee.

5. Testing fee.

The amounts for each item listed above are specified in Schedule 3.

Chapter V: Supplementary Provisions

Article 18

When executing inspection duties in accordance with these Regulations, inspection personnel shall present documents related to their official duties or display identification sufficient to verify their identity.

Article 19

These Regulations shall take effect on May 1, 2021 (Republic of China Year 110).

Amendments to these Regulations shall take effect from the date of promulgation.

Translated by RegDesk AI

附表一

項次	品目	分類分級代碼	中文名稱	英文名稱
1	4014.10.00.10	L.5300	衛生套（保險套）	Condom
2	4014.10.00.90	L.5310	含殺精劑的衛生套	Condom with spermicidal lubricant
3	6307.90.50.31-A	I.4040	一般醫用口罩	General medical mask
4	6307.90.50.31-B	I.4040	外科手術口罩	Surgical mask
5	6307.90.50.31-C	I.4040	N95醫用口罩	N95 medical mask
6	3002.15.00.10	B.4020	COVID-19家用型抗原檢測試劑	COVID-19 Antigen Home/Self Test

附表二：輸入醫療器材查核項目、檢驗項目及檢驗方法

附表一項次1：衛生套(保險套)、項次2：含殺精劑的衛生套

一、查核項目：製造業者名稱及地址(應於輸入前完成標示，非以英文標示者，應補附原製造業者說明文件)。

二、檢驗項目及檢驗方法：隨機取樣每一批五十萬個以下抽三百十五個，逾五十萬個以上抽五百個，進行下列檢驗：

檢驗項目	檢驗方法
外觀	根據CNS 6629 T2008
針孔試驗	根據CNS 6629 T2008

Appendix 1

Item No.	Product Number	Classification Code	Chinese Name	English Name
1	4014.10.00.10	L.5300	□□□□□□□□	Condom
2	4014.10.00.90	L.5310	□□□□□□□□	Condom with spermicidal lubricant
3	6307.90.50.31-A	L.4040	□□□□□□	General medical mask
4	6307.90.50.31-B	L.4040	□□□□□□□	Surgical mask
5	6307.90.50.31-C	L.4040	N95□□□□	N95 medical mask
6	3002.15.00.10	B.4020	COVID-19 □□□□□□□□□	COVID-19 Antigen Home/Self Test

Appendix 2: Inspection Items and Methods for Imported Medical Devices

Appendix 1, Item 1: Condom (Prophylactic)

Item 2: Condom with Spermicidal Lubricant

I. Sample Collection:

The manufacturer's name and address (for imports, that of the finished product manufacturer) should be indicated. Non-English names must be accompanied by supporting documents (photocopies permissible).

II. Inspection Items and Methods:

Random sampling: Each batch of 50,000-150,000 products, sample 13; each batch of over 150,000, sample 5 for the following tests:

Inspection Item	Inspection Method
Appearance	According to CNS 6629 T2008
Leakage Test	According to CNS 6629 T2008

Translated by RegDesk AI

附表一項次3：一般醫用口罩、項次4：外科手術口罩、項次5：N95醫用口罩

一、查核項目：製造業者名稱及地址(應於輸入前完成標示，非以英文標示者，應補附原製造業者說明文件)。

二、檢驗項目及檢驗方法：隨機取樣每一批抽一百片，進行下列檢驗：

一般醫用口罩

檢驗項目	檢驗方法
細菌過濾效率	根據 CNS 14774
壓差	根據 CNS 14774

外科手術口罩

檢驗項目	檢驗方法
次微米過濾效率	根據 CNS 14774
壓差	根據 CNS 14774

N95醫用口罩

檢驗項目	檢驗方法
次微米過濾效率	根據 CNS 14755
呼吸氣阻抗	根據 CNS 14755

附表一項次6：COVID-19家用型抗原檢測試劑

一、查核項目：製造業者名稱及地址(應於輸入前完成標示，非以英文標示者，應補附原製造業者說明文件)。

二、檢驗項目及檢驗方法：隨機取樣每一批抽一百劑，進行下列檢驗：

檢驗項目	檢驗方法
診斷用試劑分析反應性測試	以適當病毒株確認產品陽性、陰性反應正確性
診斷用試劑偵測極限	依產品宣稱之偵測極限病毒濃度檢測產品陽性反應性

Appendix 1, Item 3: General Medical Masks, Item 4: Surgical Masks, Item 5: N95 Medical Masks

1. Items to be inspected: Manufacturer's name and address (must match the declaration made at import. If not in English, please attach a translation of the certificate's content.)

2. Inspection items and methods: Randomly sample 100 items per batch for the following tests:

General Medical Masks

Inspection Item	Inspection Method
Bacterial Filtration Efficiency	According to CNS 14774
Differential Pressure	According to CNS 14774

Surgical Masks

Inspection Item	Inspection Method
Bacterial Filtration Efficiency	According to CNS 14774
Differential Pressure	According to CNS 14774

N95 Medical Masks

Inspection Item	Inspection Method
Particle Filtration Efficiency	According to CNS 14755
Breathing Resistance	According to CNS 14755

Appendix 1, Item 6: Testing for COVID-19 Diagnostic Reagents

1. Items to be inspected: Manufacturer's name and address (must match the declaration made at import. If not in English, please attach a translation of the certificate's content.)

2. Inspection items and methods: Randomly sample 100 items per batch for the following tests:

Inspection Item	Inspection Method
Quality Testing of Diagnostic Reagent Sensitivity	Using samples with expected concentrations: positive/negative reaction correctness
Diagnostic Reagent Specificity Test	Based on the concentration of detectable substances: reaction correctness

Page 135

Translated by RegDesk AI

附表三

項目	收費數額（新臺幣）	
一、審查費	審查費依完稅價格為基準，採下列費率計收： 輸入醫療器材之審查費率為千分之二點五；審查費不足五百元者以每件五百元計收；超過十萬元者，超過之部分減半計收。	
二、現場查核費	依「政府行政機關辦公日曆表」上班日上午八時三十分至下午五時三十分，每一處所每一檢查人次五百元。 於前項時間以外依下列規定加收： 1. 上班日上午六時至八時三十分前或下午五時三十分後至十時，每人次四百元。 2. 例假日上午六時至下午十時，每人次一千元。 3. 於前二點規定時間以外，每人次二千元。 無法當日往返，而須住宿者，另依行政院訂定國內出差旅費報支要點規定之各項費用標準計收。	
三、通知書費	輸入醫療器材許可通知書及查驗不符合通知書之補發、換發、加發或變更登載事項之費用，每份一百元。	
四、電腦傳送訊息更正費	因可歸責於報驗義務人或代理人之事由，申請更正電腦傳送訊息時，每件計收一百元，費用包含換發登載該次更正內容之輸入醫療器材許可通知書一份。	
五、檢驗費	輸入醫療器材進行複驗或因抽批查驗不合格回復逐批查驗之檢驗費用。	
項目	說明	收費項目及數額
衛生套外觀	外觀可見缺點（嚴重及非嚴重）	依「食品藥物化粧品檢驗封緘及對照標準品供應收費標準」，檢驗項目「編號A001：一般檢查」收費。
衛生套針孔試驗	根據CNS 6629	依「食品藥物化粧品檢驗封緘及對照標準品供應收費標準」，檢驗項目「編號B006：衛生套針孔試驗」收費。
一般醫用口罩細菌過濾效率	根據 CNS14774	依「食品藥物化粧品檢驗封緘及對照標準品供應收費標準」，檢驗項目「編號B011：外科手術口罩細菌過濾效率」收費。
一般醫用口罩壓差測試	根據CNS 14774	依「食品藥物化粧品檢驗封緘及對照標準品供應收費標準」，檢驗項目「編號B012：外科手術口罩壓差測試」收費。

Appendix Three

Item | Fee Amount (New Taiwan Dollars)

I. Inspection Fee

The inspection fee is based on visual inspection. Other than the following, no additional fees will be charged:

If the customs office suggests inspections, a fee of NT$580 per entry will be charged, with a minimum of NT$500 per suggestion.

If it is more than five items, an additional fee of NT$200 per item will be charged.

II. On-Site Inspection

According to the regular working hours of government authorities, Monday to Friday, 8:30 AM to 5:30 PM; exceeding 5:30 PM to 8:00 AM the next day, an additional NT$500 per hour per person is charged.

If the inspection is required:

1. Monday to Friday before 8:00 AM or after 5:30 PM; Saturday 8:00 AM to 12:00 PM, NT$800 per hour per person.

2. Example: 8:00 AM to 5:00 PM, NT$400 per hour per person.

3. Apart from the above regulations, NT$2,000 per person per hour on holidays.

If there are no waiting rooms, other fees related to venue rental etc., will be billed by presentation of receipts.

III. Communication Fees

If the Customs Office needs to use the telephone or other communication equipment for inspection, changing inspection items, consultation, reporting, etc., NT$7 will be charged per year.

IV. CD-ROM Information Supplementary Fee

If there is a need to provide results in CD-ROM format, an additional fee of NT$100 per report per item shall be added to the inspection fee.

V. Re-inspection Fee

Re-inspection due to incorrect results from previous inspection or other factors shall be charged according to the following items:

Item	Description	Fee Project Mark and Description
Fresh Items with Visual Inspection	Visible or odor change (either rust, mold, or weight reduction)	According to “Food Commodity Chemical Inspection Fee Collection Standard.” Inspection item code: A001. Fresh items with visual inspection.
Street Alcohol Density Tester	Based on CNS 662	According to “Food Commodity Chemical Inspection Fee Collection Standard.” Inspection item code: B006. Street alcohol density tester inspection.
General-purpose Mask Filtration Efficiency	Based on CNS 14774	According to “Food Commodity Chemical Inspection Fee Collection Standard” Inspection item code: B011. Non-medical mask filtration efficiency inspection.

Translated by RegDesk AI

General-purpose Ma Respiratory Resistance	**Based on CNS 14774**	**According to “Food Commodity Chemical Inspection Fee Collection Standar Inspection item code: B012. Non-medical mask respiratory resistance inspection.**

136

Translated by RegDesk AI

外科手術口罩壓差測試	根據CNS 14774	依「食品藥物化粧品檢驗封緘及對照標準品供應收費標準」，檢驗項目「編號B012：外科手術口罩壓差」收費。
次微米過濾效率	根據CNS 14774或CNS 14755	依「食品藥物化粧品檢驗封緘及對照標準品供應收費標準」，檢驗項目「編號B015：次微米過濾效率」收費。
呼吸器阻抗	根據CNS 14755	依「食品藥物化粧品檢驗封緘及對照標準品供應收費標準」，檢驗項目「編號B015：次微米過濾效率」收費。
備註：以外幣為貨款核算查驗規費者，按財政部關務署訂定之每旬報關適用外幣匯率表換算為新臺幣。		

Surgical Mask Compression Test	According to CNS 14774	According to "Food Product Biodegradable Inspection Test Fee Table charges. Inspection Item Code B012: Surgical Mask Compression Te	C...
Microbial Filtration Efficiency	According to CNS 14774 or CNS 14755	According to "Food Product Biodegradable Inspection Test Fee Table" charges. Inspection Item Code B015: Microbial Filtration Efficiency	C...
Respirator Resistance	According to CNS 14755	According to "Food Product Biodegradable Inspection Test Fee Table" charges. Inspection Item Code B015: Microbial Filtration Efficiency	C...

Note: The above are the test items and charges for overseas identity inspection applicants. According to the regulations of the Financial and Economic Times Bureau, every January, the applicable overseas applicant fee schedule will be updated.

Translated by RegDesk AI

【醫療器材回收處理辦法】(110.04.28發布)

第1條

本辦法依醫療器材管理法（以下簡稱本法）第五十八條第三項規定訂定之。

第2條

本法第五十八條第一項各款應回收之醫療器材，分為下列三級：

一、第一級：

（一）第一款醫療器材、第二款不良醫療器材及第三款醫療器材：經中央主管機關認定有重大危害使用者人體健康或有重大危害之虞。

（二）第二款：未取得許可證或登錄。

二、第二級：

（一）第一款醫療器材、第二款不良醫療器材：經中央主管機關認定無危害、非有重大危害使用者人體健康或無危害之虞。

（二）第三款醫療器材：經中央主管機關認定無重大危害使用者人體健康之虞。

三、第三級：第四款及第五款醫療器材。

第3條

本法第二十五條醫療器材許可證所有人或登錄者，應依下列期限，辦理回收完畢：

一、第一級：自公告之次日或依法認定應回收之日起一個月內。

二、第二級：自公告之次日或依法認定應回收之日起二個月內。

三、第三級：自本法第二十二條第二項製造許可廢止之次日起或依法認定應回收之日起六個月內。

第4條

醫事機構及醫療器材商，應自中央主管機關公告、依法認定或製造許可廢止之日起，停止醫療器材輸入、製造、批發、零售或意圖販賣而陳列。

本辦法回收之醫療器材市售品及庫存品，應依下列規定處理：

一、本國製造：經查核或檢驗後仍可改製使用者，由直轄市、縣（市）主管機關派員監督原製造廠商限期改製；其不能改製或屆期未改製者，沒入銷燬之。

二、國外輸入：即行封存，並由直轄市、縣（市）主管機關令原進口商限期退運出口；屆期未能退貨者，沒入銷燬之。

138

[Regulations for the Recall and Disposal of Medical Devices] (Promulgated on 2021.04.28)

Article 1

These Regulations are enacted pursuant to Paragraph 3, Article 58 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

Medical devices subject to recall as listed in Paragraph 1, Article 58 of the Act are categorized into the following three classes:

1. Class 1:

(1) Medical devices under Item 1, defective medical devices under Item 2, and medical devices under Item 3: as determined by the central competent authority to pose or potentially pose a significant hazard to the user's health.

(2) Item 2: those without approval certificates or registration.

2. Class 2:

(1) Medical devices under Item 1, and defective medical devices under Item 2: as determined by the central competent authority to not pose or not potentially pose a significant hazard to the user's health.

(2) Medical devices under Item 3: as determined by the central competent authority to not potentially pose a significant hazard to the user's health.

3. Class 3: Medical devices under Items 4 and 5.

Article 3

The holder of a medical device license or the registrant as referred to in Article 25 of the Act shall complete the recall within the following time limits:

1. Class 1: Within one month from the day following the public announcement or the date the recall is determined in accordance with the law.

2. Class 2: Within two months from the day following the public announcement or the date the recall is determined in accordance with the law.

3. Class 3: Within six months from the day following the revocation of the manufacturing permit pursuant to Paragraph 2, Article 22 of the Act or from the date the recall is determined in accordance with the law.

Article 4

Medical institutions and medical device businesses shall, from the date of public announcement or lawful determination by the central competent authority, or from the date of revocation of the manufacturing permit, cease import, manufacture, wholesale, retail, or display for the purpose of sale of the medical devices.

Medical devices for sale and in stock subject to recall under these Regulations shall be handled as follows:

1. Domestically manufactured: If, after inspection or verification, the devices can be modified for use, the municipal or county (city) competent authority shall assign personnel to supervise the original manufacturer to make such modifications within a prescribed period; devices that cannot be modified or are not modified within the prescribed period shall be confiscated and destroyed.

Translated by RegDesk AI

2. Imported: The devices shall be immediately sealed, and the municipal or county (city) competent authority shall order the original importer to return them for export within a prescribed period; devices that are not returned within the prescribed period shall be confiscated and destroyed.

Translated by RegDesk AI

第5條

直轄市、縣（市）主管機關通知醫療器材商啟動醫療器材回收作業時，應通報中央及其他直轄市、縣（市）主管機關。

第6條

各級主管機關對於應回收之醫療器材，得於機關網站或大眾傳播媒體，公布下列資料：

一、品名、許可證或登錄字號。

二、規格、批號或序號之識別資料。

三、醫療器材許可證所有人或登錄者之名稱及地址。

四、回收原因。

第7條

醫療器材許可證所有人或登錄者應訂定醫療器材回收作業規定，並據以執行，其規定內容如下：

一、回收作業之組織。

二、回收人員及任務。

三、回收作業計畫書。

四、回收之通知方式。

五、回收及處理方式。

六、回收成果報告書。

第8條

前條第四款通知之收受者，為醫療器材許可證所有人或登錄者之直接銷售對象。

前項通知之內容，應包括下列事項：

一、醫療器材許可證所有人或登錄者之名稱、地址及電話。

二、醫療器材製造業者名稱及地址。

三、醫療器材之品名、規格及許可證或登錄字號。

四、醫療器材批號或序號之識別資料及編號。

五、回收之原因及其可能產生之危害。

六、回收方式、回收交付之時間及地點。

七、直接銷售對象應配合之事項。

醫療器材許可證所有人或登錄者，應依下列期限，完成第一項通知：

一、第一級及第二級：自公告之次日或依法認定之日起二十四小時內。

二、第三級：自製造許可廢止之次日或依法認定應回收之日起一星期內。

Article 5

When the municipal or county (city) competent authority notifies medical device firms to commence medical device recall operations, it shall also notify the central competent authority and other municipal or county (city) competent authorities.

Article 6

Competent authorities at all levels, with respect to medical devices subject to recall, may publicize the following information on the agency's website or via mass media:

1. Product name, license or registration number.

2. Specifications, batch number, or serial number identification data.

3. Name and address of the medical device license holder or registrant.

4. Reason for the recall.

Article 7

The medical device license holder or registrant shall establish and implement medical device recall operation procedures, the content of which shall include the following:

1. Organization of recall operations.

2. Recall personnel and their duties.

3. Recall operation plan.

4. Notification methods for the recall.

5. Recall and handling methods.

6. Recall results report.

Article 8

The recipients of the notification stipulated in subparagraph 4 of the preceding article shall be the direct sales targets of the medical device license holder or registrant.

The content of the aforementioned notification shall include the following:

1. Name, address, and telephone number of the medical device license holder or registrant.

2. Name and address of the medical device manufacturer.

3. Product name, specification, and license or registration number of the medical device.

4. Identification data and number of the medical device batch or serial number.

5. Reason for recall and possible hazards.

6. Recall method, as well as the date and location for recall delivery.

7. Matters the direct sales targets shall comply with.

The medical device license holder or registrant shall complete the notification in Paragraph 1 within the following timeframes:

1. Class I and Class II: Within twenty-four hours from the day following the public announcement or from the date recognized according to the law.

2. Class III: Within one week from the day following the revocation of the manufacturing license or from the date recognized according to the law as subject to recall.

Translated by RegDesk AI

醫療器材許可證所有人或登錄者，應記載執行通知之人員、直接銷售對象與接收通知之人員及通知之時間與方式。

前項通知應作成紀錄，並至少保存五年。

第9條

醫療器材許可證所有人或登錄者，執行醫療器材回收作業前，應訂定第七條第三款計畫書，報直轄市、縣（市）主管機關，並副知中央主管機關；主管機關認有修正必要者，得要求其修正。

前項計畫書，應包括下列事項：

一、醫療器材許可證所有人或登錄者之名稱、地址及電話。

二、醫療器材製造業者名稱及地址。

三、醫療器材之品名、規格及許可證或登錄字號。

四、醫療器材之批號或序號之識別資料及編號。

五、醫療器材於國內製造或輸入之總量、銷售數量及庫存量。

六、醫療器材於國內銷售之醫事機構、醫療器材商之名稱、地址及其各別之銷售數量。

七、國內製造醫療器材輸出者，其輸出之國別、對象名稱與地址及各別銷售數量。

八、回收之原因及其可能產生之危害。

九、預定完成回收之日期。

十、通知該醫療器材直接銷售之醫事機構、醫療器材商之方式與內容及其他擬採取之相關措施。

第一項計畫書報主管機關之期限如下：

一、第一級及第二級：自公告或依法認定應回收之日起三日內。

二、第三級：自製造許可廢止之次日或依法認定應回收之日起二星期內。

第10條

直轄市、縣（市）主管機關應督導轄區內醫事機構、醫療器材商，依本法第五十八條規定辦理醫療器材回收事宜。

直轄市、縣（市）主管機關應於自行啟動或自收受其他主管機關通知啟動第一級回收作業之日起十日內，至轄區內醫事機構、醫療器材商進行抽查，確認回收醫療器材下架及其他回收作業程序。

第11條

醫療器材許可證所有人或登錄者對於回收之醫療器材，連同其庫存品，應予識別及標示，並分別存放。

140

The medical device license holder or registrant shall record the personnel executing the notification, the direct sales targets, the personnel receiving the notification, as well as the time and method of notification.

Records of the notification in the preceding paragraph shall be created and retained for at least five years.

Article 9

Before executing the recall operation of medical devices, the medical device license holder or registrant shall formulate the plan specified in Subparagraph 3, Article 7, and submit it to the competent authority of the municipality or county (city), with a copy to the central competent authority; the competent authority may require amendments if deemed necessary.

The plan in the preceding paragraph shall include the following items:

1. Name, address, and telephone number of the medical device license holder or registrant.

2. Name and address of the medical device manufacturer.

3. Product name, specification, and license or registration number of the medical device.

4. Identifying information and numbers of the batch or serial number of the medical device.

5. Total quantity manufactured or imported domestically, quantity sold, and inventory quantity of the medical device.

6. For medical institutions or medical device dealers to whom the medical device was sold domestically, their names, addresses, and individual sales quantities.

7. For domestically manufactured medical devices exported, the destination countries, target names, addresses, and individual sales quantities.

8. Reasons for the recall and the potential hazards arising therefrom.

9. Scheduled date for completion of the recall.

10. Method and content of notification to the medical institutions and medical device dealers to whom the medical device was directly sold, and other related measures intended to be taken.

The deadlines for submitting the plan in Paragraph 1 to the competent authority are as follows:

Categ..	Deadline
Level 1 & 2	Within three days from the date of announcement or legal determination that a recall is required.
Level 3	Within two weeks from the day after revocation of the manufacturing license or from the date of legal determination that a recall is required.

Article 10

The municipal or county (city) competent authority shall supervise medical institutions and medical device dealers within its jurisdiction to handle medical device recalls in accordance with Article 58 of this Act.

The municipal or county (city) competent authority shall, within ten days from the day of initiating, or receiving notice from other competent authorities to initiate, a level 1 recall operation, conduct random inspections at medical institutions and medical device dealers within its jurisdiction to confirm the removal of the recalled medical devices from shelves and the implementation of other recall operation procedures.

Translated by RegDesk AI

Article 11

The medical device license holder or registrant shall identify and label the recalled medical devices and their inventories, and store them separately.

Translated by RegDesk AI

第12條

醫療器材許可證所有人或登錄者執行回收作業完成後，應製作第七條第六款成果報告書，報直轄市、縣（市）主管機關，並副知中央主管機關；主管機關認有修正必要時，得要求其修正。

前項回收成果報告書，應包括下列事項：

一、醫療器材許可證所有人或登錄者之名稱、地址及電話。

二、醫療器材製造業者名稱及地址。

三、醫療器材之品名、規格及許可證或登錄字號。

四、醫療器材之批號或序號之識別資料及編號。

五、回收醫療器材於國內製造或輸入之總量、銷售與庫存量及已回收與未回收之品項、數量。

六、各回收對象之回收品項及數量明細。

七、回收完成之日期、回收產品存放地點、預定後續處理之方法及日期。

八、後續預防矯正措施。

第一項回收成果報告書報主管機關之期限如下：

一、第一級及第二級：完成回收之日起三日內。

二、第三級：完成回收之日起二星期內。

第13條

直轄市、縣（市）主管機關應審酌醫療器材回收作業之後續處理方法及日期，對醫療器材許可證所有人或登錄者予以查核，並將查核結果報中央主管機關備查。

第14條

本辦法自中華民國一百十年五月一日施行。

141

Article 12

After the completion of the recall operation, the medical device license holder or registrant shall prepare a results report as specified in Subparagraph 6, Article 7, and submit it to the municipal or county (city) competent authority, with a copy to the central competent authority; if the competent authority deems corrections necessary, it may require such corrections.

The recall results report in the preceding paragraph shall include the following items:

1. Name, address, and telephone number of the medical device license holder or registrant.

2. Name and address of the medical device manufacturer.

3. Product name, specifications, and license or registration number of the medical device.

4. Batch number or serial number identification data and number of the medical device.

5. Total quantity manufactured or imported domestically, quantity sold, stock quantity, and the recalled and unrecalled items, quantities of the recalled medical device.

6. Detailed breakdown of recalled items and quantities for each recall target.

7. Date of completion of recall, storage location of the recalled products, intended subsequent handling methods and dates.

8. Subsequent preventive and corrective measures.

The deadlines for submission of the recall results report referred to in Paragraph 1 to the competent authority are as follows:

1. Class I and Class II: within three days from the date of completion of the recall.

2. Class III: within two weeks from the date of completion of the recall.

Article 13

The municipal or county (city) competent authority shall, after considering the subsequent handling methods and dates for the medical device recall operation, verify the medical device license holder or registrant, and report the verification results to the central competent authority for record.

Article 14

These Regulations shall take effect on May 1, 2021.

Translated by RegDesk AI

【醫療器材行政規費收費標準】(112.02.23修正)

第1條

本標準依醫療器材管理法第七十六條第二項及規費法第十條規定訂定之。

第2條

辦理下列醫療器材各項申請案件，每件應繳納之費用如下：

一、查驗登記：

（一）全球首創無類似品，應執行國外製造業者查核：新臺幣二十五萬元。

（二）優先審查：新臺幣十八萬元。

（三）新原理、新結構、新材料、新效能或無類似品：新臺幣十三萬元。

（四）第三等級醫療器材：新臺幣十萬元。

（五）第二等級醫療器材：新臺幣五萬八千元。

（六）第一等級醫療器材：新臺幣一萬五千元。

（七）專供外銷醫療器材：新臺幣一萬五千元。。

二、許可證登記事項變更及展延：

（一）效能、用途或適應症變更：新臺幣四萬元。

（二）變更規格：新臺幣三萬五千元。

（三）未涉及安全及效能評估之尺寸規格變更：新臺幣二萬五千元。

（四）移轉、合併、產地或遷廠變更：新臺幣二萬五千元。

（五）其他變更：新臺幣一萬元。

（六）許可證之標籤或說明書核定本補發：新臺幣一萬元。

（七）原核准許可證有效期間展延：新臺幣八千元。

三、許可證領證、補發或換發：新臺幣一千五百元。

四、登錄、年度申報及登錄事項變更：

（一）醫療器材登錄：新臺幣一萬元。

（二）醫療器材年度申報：新臺幣二千元。

（三）醫療器材登錄之變更：新臺幣八千元。

五、臨床試驗：

（一）臨床試驗計畫書審核：新臺幣五萬元。

（二）臨床試驗報告書審查：新臺幣五萬元。

（三）臨床試驗文件技術性評估：新臺幣二萬元。

（四）臨床試驗變更審查：新臺幣五千元。

142

[Standards for the Collection of Administrative Fees for Medical Devices] (Amended on 2023.02.23)

Article 1

These standards are established in accordance with Paragraph 2, Article 76 of the Medical Devices Act and Article 10 of the Charges Act.

Article 2

For handling the following types of medical device applications, the fees payable per application are as follows:

1. Registration and Review:

(1) First-in-the-world, with no similar products, requiring foreign manufacturer verification: NT$250,000.

(2) Priority Review: NT$180,000.

(3) New principle, new structure, new material, new functionality, or no similar product: NT$130,000.

(4) Class III medical devices: NT$100,000.

(5) Class II medical devices: NT$58,000.

(6) Class I medical devices: NT$15,000.

(7) Medical devices exclusively for export: NT$15,000.

2. Changes and Extensions of License Registration Items:

(1) Changes in performance, use, or indications: NT$40,000.

(2) Change in specifications: NT$35,000.

(3) Change in dimensions or specifications not involving safety or performance evaluation: NT$25,000.

(4) Transfer, merger, change in place of origin, or relocation of manufacturing facility: NT$25,000.

(5) Other changes: NT$10,000.

(6) Re-issuance of approved license labels or instructions: NT$10,000.

(7) Extension of original approved license validity period: NT$8,000.

3. Issuance, re-issuance, or replacement of a license: NT$1,500.

4. Registration, annual declaration, and changes to registration items:

(1) Medical device registration: NT$10,000.

(2) Medical device annual declaration: NT$2,000.

(3) Change in medical device registration: NT$8,000.

5. Clinical Trials:

(1) Review of clinical trial protocol: NT$50,000.

(2) Review of clinical trial report: NT$50,000.

(3) Technical evaluation of clinical trial documentation: NT$20,000.

(4) Review of clinical trial amendments: NT$5,000.

Translated by RegDesk AI

（五）國外優良臨床試驗實地查核：每次每一國家（地區）新臺幣六十五萬元。

（六）國內優良臨床試驗實地查核：每次新臺幣四萬五千元。

六、品質管理系統檢查：

（一）國內醫療器材品質管理系統檢查及其後續管理檢查：新臺幣六萬元。

（二）國外醫療器材品質管理系統文件檢查或其後續檢查：新臺幣六萬元。

（三）醫療器材製造許可增加登錄品項、內容或遷廠之變更：新臺幣六萬元。

（四）醫療器材製造許可之其他變更：新臺幣一萬元。

（五）國外醫療器材品質管理系統實地檢查或其後續檢查：新臺幣六十萬元。

（六）國外醫療器材製造許可增加登錄品項、內容之實地檢查：新臺幣六十萬元。

（七）國外醫療器材製造許可遷廠之實地檢查：新臺幣六十萬元。

（八）前三目收費項目，每件每增加一醫療器材品項製程，增加收費如下：

1.同一廠房：加收新臺幣三萬五千元。

2.不同廠房：加收新臺幣十萬五千元。

（九）國外醫療器材品質管理系統實地檢查：每件每增加一不同滅菌製程，增加收費新臺幣十萬五千元。

（十）國外醫療器材品質管理系統實地檢查：每件每增加一委外製造廠，增加收費新臺幣三十萬元。

（十一）醫療器材製造業者符合醫療器材品質管理系統準則第七十八條規定之檢查或其後續檢查：新臺幣三萬元。

（十二）優良運銷系統檢查或其後續檢查（含一倉庫）：新臺幣三萬元，每件每增加一倉庫，增加收費新臺幣一萬元。

（十三）醫療器材運銷許可登記事項之變更：新臺幣一萬元。

七、相關文件申請：

（一）屬性管理查詢：新臺幣三千五百元。

（二）自用原料申請：新臺幣六千元。

（三）許可證授權申請：新臺幣四千元。

（四）中文、英文製（銷）售證明書：新臺幣一千八百元。

143

(5) On-site inspection of foreign Good Clinical Practice (GCP) trials: NT$650,000 per country (region) for each inspection.

(6) On-site inspection of domestic Good Clinical Practice (GCP) trials: NT$45,000 per inspection.

6. Quality Management System Inspections:

(1) Inspection of domestic medical device quality management system and subsequent management inspections: NT$60,000.

(2) Document inspection or subsequent inspection of foreign medical device quality management system: NT$60,000.

(3) Addition of registration items, content, or plant relocation for medical device manufacturing permits: NT$60,000.

(4) Other changes to medical device manufacturing permits: NT$10,000.

(5) On-site inspection or subsequent inspection of foreign medical device quality management systems: NT$600,000.

(6) On-site inspection for addition of registration items or content to foreign medical device manufacturing permits: NT$600,000.

(7) On-site inspection for relocation of plant under foreign medical device manufacturing permit: NT$600,000.

(8) For the above three charging items, for each additional medical device item manufacturing process per case, additional fees are charged as follows:

1. Same plant: an additional NT$35,000.

2. Different plant: an additional NT$105,000.

(9) On-site inspection of foreign medical device quality management system: for each additional different sterilization process per case, an additional NT$105,000 is charged.

(10) On-site inspection of foreign medical device quality management system: for each additional outsourced manufacturer per case, an additional NT$300,000 is charged.

(11) Inspection or subsequent inspection for compliance with Article 78 of the Medical Device Quality Management System Regulations by the medical device manufacturer: NT$30,000.

(12) Inspection or subsequent inspection of Good Distribution Practice (GDP) system (including one warehouse): NT$30,000; for each additional warehouse per case, an additional NT$10,000 is charged.

(13) Change of registration matters for medical device distribution permit: NT$10,000.

7. Application for Related Documents:

(1) Attribute management inquiry: NT$3,500.

(2) Application for raw materials for personal use: NT$6,000.

(3) Application for permit license authorization: NT$4,000.

(4) Certificate of (sale) for Chinese or English version: NT$1,800.

Translated by RegDesk AI

（五）中文、英文製造許可證明文件及其補發：新臺幣一千八百元。

（六）優良運銷證明文件及其補發：新臺幣一千八百元。

（七）委託製造申請：新臺幣四千元。

（八）委託製造變更申請：新臺幣二千元。

八、專案申請：

（一）改進製造、研究、試驗、危急重大或嚴重失能、展示：新臺幣一萬元。

（二）因應緊急公共衛生情事製造或輸入：新臺幣二萬元。

（三）個人自用：新臺幣二千元。

（四）國貨復運：新臺幣一萬二千元。

九、廣告審查：

（一）新申請：新臺幣一萬元。

（二）展延申請：新臺幣五千元。

（三）核定表遺失補發：新臺幣二千五百元。

十、案件函詢：

（一）函詢醫療器材查驗登記、登錄、臨床試驗、製造品質檢查及運銷管理：新臺幣四千元。

（二）函詢全國醫療器材不良反應通報資料庫資料：新臺幣四千元。

十一、醫療器材商許可執照：

（一）申請登記：新臺幣一千五百元。

（二）登記事項變更：新臺幣一千元前項第二款第四目變更申請，每件以一廠次為限。

前項第二款第四目變更申請，每件以一廠次為限。

第一項第七款第四目、第五目醫療器材相關文件申請，每件以一式三份為限。

第一項第七款第四目中文、英文製（銷）售證明書申請，每件以一許可證為限。

第一項第八款第四目專案申請，每件以十項產品為限。

第3條

中央主管機關辦理前條第一項第一款第一目、第五款第五目及第六款第五目至第十目之查核，查核人員及專家之臨場費，應比照國外出差旅費報支要點之規定，向被查核者收取。

第4條

本標準自中華民國一百十二年三月一日施行。

144

(5) Chinese and English manufacturing license certificates and their reissuance: NT$1,800.

(6) Good distribution practice certificates and their reissuance: NT$1,800.

(7) Contract manufacturing application: NT$4,000.

(8) Contract manufacturing change application: NT$2,000.

8. Special Project Application:

(1) Improvement of manufacturing, research, testing, emergency or severe disability cases, exhibition: NT$10,000.

(2) Manufacture or import in response to emergency public health events: NT$20,000.

(3) Personal use: NT$2,000.

(4) Re-export of domestic goods: NT$12,000.

9. Advertisement Review:

(1) New application: NT$10,000.

(2) Extension application: NT$5,000.

(3) Reissuance of approval document lost: NT$2,500.

10. Official Correspondence Inquiries:

(1) Inquiries regarding medical device registration, listing, clinical trials, manufacturing quality inspection, and distribution management: NT$4,000.

(2) Inquiries regarding the National Medical Device Adverse Reaction Reporting Database: NT$4,000.

11. Medical Device Business Permit:

(1) Application for registration: NT$1,500.

(2) Change of registered items: NT$1,000 (for each application for change under Item 2, Sub-item 4, limited to one manufacturer per application).

Each change application under Item 2, Sub-item 4 above is limited to one manufacturer per case.

For applications for medical device-related documents under Item 7, Sub-items 4 and 5 of Paragraph 1 above, each case is limited to three copies.

For applications for Chinese and English certificates of (manufacturing/sales) under Item 7, Sub-item 4 of Paragraph 1 above, each case is limited to one certificate per permit.

For each special project application under Item 8, Sub-item 4 of Paragraph 1 above, each case is limited to ten products.

Article 3

For on-site inspections conducted by the central competent authority as per Item 1, Sub-item 1, Item 5, Sub-item 5, and Items 6, Sub-items 5 to 10 of the preceding Article, the on-site allowances for inspectors and experts shall be collected from the entity being inspected in accordance with the provisions for overseas travel allowances.

Article 4

These Standards shall take effect on March 1, 2023 (ROC Year 112).

Translated by RegDesk AI

【醫療器材檢驗委任或委託作業辦法】(110.04.30發布)

第1條

本辦法依醫療器材管理法第七十七條規定訂定之。

第2條

各級主管機關，得將醫療器材檢驗之全部或一部，委任或委託相關機關（構）執行。

前項受委任機關（構），在中央為衛生福利部食品藥物管理署或其他所屬機關（構）；在地方由直轄市、縣（市）主管機關委任所屬機關（構）；其權利義務關係，由委任機關定之。

第3條

前條受委託機關（構）、法人或團體，應符合下列條件：

一、具備檢驗項目之檢驗能力、相關場所、設施及設備。

二、訂有檢驗作業程序及品質保證計畫。

第4條

委託者應與受託者訂定委託契約；其內容應包括下列事項：

一、委託項目。

二、委託期程。

三、委託者之監督與稽核權利及機制。

四、受託者因執行受託事項所知悉或持有之個人資料及營業秘密之保密義務。

五、契約解除及終止條件。

六、契約解除及終止後，受託者之義務。

七、契約爭議處理機制。

八、其他權利義務事項。

第5條

受託者於接受委託檢驗之醫療器材檢體時，應出具收據，並負保管義務。

受託者完成檢驗後，應出具檢驗報告書予委託者；必要時，得依委託者之要求，先以電子方式傳送檢驗結果。

第6條

前條第二項檢驗報告書，應記載下列事項：

一、檢驗報告書編號或其他可供識別之資料。

二、受託者名稱、地址、電話及其他相關事項。

三、委託者名稱、地址及委託檢驗單號碼。

145

[Regulations Governing the Commissioning or Entrustment of Medical Device Inspection]
(Promulgated on 2021.04.30)

Article 1

These Regulations are enacted pursuant to the provisions of Article 77 of the Medical Devices Act.

Article 2

Competent authorities at all levels may commission or entrust all or part of medical device inspections to relevant agencies (institutions) for execution.

The commissioned agencies (institutions) referred to in the preceding paragraph, at the central level, shall be the Food and Drug Administration, Ministry of Health and Welfare, or other affiliated agencies (institutions); at the local level, they shall be agencies (institutions) affiliated to the competent authority of a special municipality or county (city); the rights and obligations of such relationships shall be prescribed by the commissioning agency.

Article 3

The entrusted agencies (institutions), legal persons, or organizations referred to in the preceding article shall meet the following conditions:

1. Possess the inspection capabilities, relevant premises, facilities, and equipment required for the inspection items.

2. Establish inspection operation procedures and a quality assurance plan.

Article 4

The entrusting party shall enter into an entrustment contract with the entrusted party; the content thereof shall include the following matters:

1. Commissioned items.

2. Duration of the commission.

3. Supervisory and audit rights and mechanisms of the entrusting party.

4. Obligations of confidentiality regarding personal data and trade secrets known to or held by the entrusted party due to execution of entrusted matters.

5. Conditions for contract rescission and termination.

6. Obligations of the entrusted party after rescission or termination of the contract.

7. Mechanisms for dispute resolution under the contract.

8. Other matters pertaining to rights and obligations.

Article 5

Upon acceptance of medical device samples for inspection pursuant to commission, the entrusted party shall issue a receipt and be responsible for their safekeeping.

After completing the inspection, the entrusted party shall issue an inspection report to the entrusting party; when necessary, the inspection results may be transmitted electronically upon the request of the entrusting party.

Article 6

The inspection report referred to in Paragraph 2 of the preceding article shall specify the following items:

Translated by RegDesk AI

1. Inspection report number or other information for identification.
2. Name, address, telephone number, and other relevant details of the entrusted party.
3. Name, address, and the commissioned inspection form number of the entrusting party.

Translated by RegDesk AI

四、醫療器材檢體名稱或代碼、外觀或物理性狀描述與照片、收受日期、執行檢驗日期、檢驗方法、檢驗結果及契約指定相關項目。

五、醫療器材檢體之廠牌、型號、序號或批號、製造廠、許可證字號、製造日期、有效期間或保存期限及其他檢體資訊。

六、報告日期及檢驗報告書簽署人或負責人之簽名或蓋章。

第7條

受託者經委託者同意，得將技術性事項委由符合第三條所定條件之第三人辦理；並於檢驗報告書載明第三人出具之檢驗報告編號或其他可供追溯之識別資料。

第8條

受託者對受託內容及其檢驗結果，應負保密義務，不得擅自對外洩露。

第9條

本辦法自中華民國一百十年五月一日施行。

4. The name or code of the medical device specimen, description and photograph of appearance or physical characteristics, date of receipt, date of inspection, inspection method, inspection results, and contractually designated relevant items.

5. The brand, model, serial number or lot number, manufacturer, license number, manufacturing date, validity period or expiration date, and other specimen information of the medical device specimen.

6. Report date and the signature or seal of the signatory or responsible person on the inspection report.

Article 7

With the consent of the consignor, the consignee may subcontract technical matters to a third party who meets the conditions set forth in Article 3, and shall specify in the inspection report the inspection report number or other traceable identification data issued by the third party.

Article 8

The consignee shall have the duty of confidentiality regarding the content of the commission and its inspection results and shall not disclose them to external parties without authorization.

Article 9

These Regulations shall be enforced as of May 1, 2021 (the 110th year of the Republic of China).

Translated by RegDesk AI

【醫療器材檢驗機構認證及委託認證管理辦法】(110.04.29發布)

第一章　總則

第1條

本辦法依醫療器材管理法（以下簡稱本法）第七十八條第一項及第二項規定訂定之。

第2條

本辦法用詞，定義如下：

一、檢驗機構：指具有醫療器材檢驗能力之檢驗機關（構）、法人或團體。

二、認證：指依本辦法所定之程序，對於檢驗機構就特定檢驗項目具備檢驗能力之確認。

第二章　檢驗機構認證條件及程序

第3條

申請認證之檢驗機構，應有專屬實驗室；其實驗室應符合下列條件：

一、具備必要檢驗設備、場地及品質管理系統，並能自行執行檢驗。

二、置實驗室負責人、報告簽署人、技術主管、品質主管及檢驗人員；其應具備之資格如下：

（一）學歷：國內大專校院，或符合大學、專科學校辦理國外學歷採認相關法規規定之國外大專校院以上電子、生物醫學工程、醫藥、化學、生物、生命科學或其他相關科、系、所畢業。

（二）經歷：

1.實驗室負責人、報告簽署人、技術主管及品質主管：經品質管理相關專業訓練，且具三年以上檢驗相關工作年資。

2.檢驗人員：經檢驗業務訓練。

前項第二款第二目之1工作年資，得以同款第一目學歷抵充；碩士學位抵充一年，博士學位抵充二年。同等學位採計一次，並以其最高學位抵充。

第4條

檢驗機構應填具申請書，並檢具下列文件、資料，向中央主管機關申請認證：

一、符合前條所定條件之證明。

二、檢驗能力之證明。

三、依中央主管機關公告之檢驗機構實驗室品質系統基本規範編製之下列文件：

147

Regulations for the Accreditation and Delegated Accreditation Management of Medical Device Testing Institutions (Promulgated on 2021.04.29)

Chapter 1 General Provisions

Article 1

These Regulations are enacted in accordance with Paragraphs 1 and 2, Article 78 of the Medical Devices Act (hereinafter referred to as "the Act").

Article 2

Terms used in these Regulations are defined as follows:

1. Testing Institution: Refers to an organization, legal entity, or group with the capability to test medical devices.

2. Accreditation: Refers to the confirmation, in accordance with the procedures stipulated in these Regulations, of a testing institution’s capability to perform specific testing items.

Chapter 2 Conditions and Procedures for Accreditation of Testing Institutions

Article 3

A testing institution applying for accreditation shall have a dedicated laboratory; its laboratory shall meet the following conditions:

1. Possess the necessary testing equipment, premises, and quality management system, and be able to independently perform testing.

2. Appoint a laboratory head, report signatory, technical supervisor, quality supervisor, and testing personnel; their qualifications shall be as follows:

(a) Academic background: Graduation from a domestic college or university, or from an overseas college or university at bachelor’s degree level or above in electronics, biomedical engineering, medicine and pharmacy, chemistry, biology, life sciences, or other related departments or institutes, recognized according to relevant regulations on recognition of foreign academic credentials by universities and technical colleges.

(b) Experience:

1. Laboratory head, report signatory, technical supervisor, and quality supervisor: Have received professional training in quality management and possess more than three years of relevant work experience in testing.

2. Testing personnel: Have received training in testing operations.

The work experience requirement in Item 1 of Subparagraph 2 of the preceding paragraph may be offset by the academic background in Item (a) of the same subparagraph; a master's degree may offset one year, a doctoral degree may offset two years. Only the highest degree may be counted for offsetting, and each equivalent degree is counted only once.

Article 4

The testing institution shall fill in the application form and submit the following documents and information to the central competent authority to apply for accreditation:

1. Proof of meeting the requirements set forth in the preceding article.

2. Proof of testing capability.

Translated by RegDesk AI

3. The following documents prepared in accordance with the basic specifications for quality systems of laboratory testing institutions announced by the central competent authority:

Translated by RegDesk AI

（一）品質手冊。

（二）檢驗方法標準作業程序，其內容包括檢驗結果品質管制之措施。

（三）申請定量檢驗項目者，應提供其量測不確定度之評估報告。

（四）申請認證檢驗項目之檢驗方法確效試驗評估報告。

（五）認證檢驗項目之檢驗報告出具格式、報告簽署人中文正楷簽名。

四、實驗室位置簡圖及檢驗設施配置圖。

第5條

前條文件、資料與規定不符或內容不全者，中央主管機關應通知申請者限期補正；屆期未補正者，不予受理。

第6條

中央主管機關對於檢驗機構之申請，應進行書面審查及實地查核。

實地查核結果認有缺失者，檢驗機構應依實地查核之報告，自查核結束之日起六十日內，將改善報告送中央主管機關進行複評。

第7條

第四條申請案經審核通過者，中央主管機關應發給認證證明書，並公告之。

第8條

認證證明書應載明下列事項：

一、檢驗機構名稱。

二、實驗室名稱、地址及負責人姓名。

三、經認證之檢驗項目、檢驗方法、檢驗範圍及報告簽署人。

四、認證證明書核發之年、月、日及認證編號。

五、認證有效期間。

檢驗機構應將認證證明書揭示於該機構明顯處所。

第9條

認證證明書有效期間為三年；有展延必要者，應於期滿六個月前至八個月間申請，每次展延期間，以三年為限。

申請展延應具備之文件、資料及程序，準用第四條至第六條規定；除第四條第二款外，其餘各款所定文件、資料，於前次申請認證或展延後未變動者，免予檢具。

依第一項所定期間申請展延，中央主管機關未能於原認證效期內作出准駁處分者，原認證之效力延長至准駁處分之日。

148

(1) Quality Manual.

(2) Standard Operating Procedures for inspection methods, including measures for quality control of inspection results.

(3) For those applying for quantitative inspection items, an evaluation report on the measurement uncertainty should be provided.

(4) Evaluation report of method validation tests for inspection items applying for certification.

(5) Format of inspection reports for certified inspection items, with the report signer’s name signed in standard Chinese script.

4. Simplified map of the laboratory location and layout diagram of inspection facilities.

Article 5

If the documents and materials in the preceding article do not comply with regulations or are incomplete, the central competent authority shall notify the applicant to make corrections within a specified period; applications not corrected within the deadline will not be accepted.

Article 6

The central competent authority shall conduct documentary review and on-site inspection for applications from inspection institutions.

If deficiencies are found as a result of the on-site inspection, the inspection institution shall submit an improvement report to the central competent authority for re-evaluation within sixty days from the conclusion of the inspection, based on the on-site inspection report.

Article 7

If an application under Article 4 is approved, the central competent authority shall issue a Certificate of Accreditation and announce it publicly.

Article 8

The Certificate of Accreditation shall specify the following matters:

1. Name of the inspection institution.

2. Name, address, and name of the person in charge of the laboratory.

3. Accredited inspection items, inspection methods, inspection scope, and report signer.

4. Year, month, and day of issuance of the Certificate of Accreditation and the certificate number.

5. Valid period of accreditation.

The inspection institution shall display the Certificate of Accreditation in a prominent place within the institution.

Article 9

The validity period of the Certificate of Accreditation shall be three years. If extension is necessary, an application shall be made between six to eight months before expiry. Each extension period shall be limited to three years.

The documents, materials, and procedures required for extension application shall be governed mutatis mutandis by the provisions of Articles 4 to 6; except for Item 2 of Article 4, other documents and materials that have not changed since the last accreditation or extension application may be exempted from submission.

Translated by RegDesk AI

If an application for extension is made within the period specified in Paragraph 1 and the central competent authority is unable to make a decision before the original accreditation expires, the validity of the original accreditation shall be extended until the date of decision.

Translated by RegDesk AI

第三章　認證檢驗機構之管理

第10條

第八條第一項第一款至第三款所定事項變更時，檢驗機構應於下列規定期間內，向中央主管機關申請變更：

一、實驗室地址變更：自事實發生之日起三十日。

二、檢驗方法之依據變更：自事實發生之日起九十日。

三、醫療器材特定規格及性能修正致檢驗範圍變更：自生效之日起九十日。

四、檢驗機構名稱、實驗室名稱、實驗室負責人或報告簽署人變更：自事實發生之日起九十日。

前項申請，必要時，中央主管機關得進行實地查核。

第11條

前條第一項第一款為搬遷之變更者，應於搬遷十五日前，向中央主管機關提報搬遷計畫。

前項計畫，應包括下列項目：

一、搬遷之時程。

二、實驗室新地址及位置簡圖。

三、檢驗儀器清單及檢驗設施配置圖。

第12條

檢驗機構專屬實驗室，因故不能依認證之內容執行檢驗者，應自事實發生之日起七日內通知中央主管機關；其恢復時，亦同。

第13條

檢驗機構應依第四條第三款第一目品質手冊及第二目檢驗方法標準作業程序執行檢驗，並應遵行下列規定：

一、接受委託檢驗時，與委託者訂定書面檢驗委託契約，載明委託檢驗項目、檢驗方法、檢驗範圍、委託檢驗項目之認證狀況及其他事項。委託事項有變更者，於檢驗委託契約載明變更內容及理由，並經雙方當事人確認及記錄。

二、詳實記錄委託者資料、檢驗報告用途。

三、詳實記錄樣品之收樣狀態，包括產品名稱、批號、製造或有效日期、來源、包裝及數量之樣品資訊，不得空白，並就送驗樣品照相留存。

四、檢驗報告註明樣品資訊、檢驗項目、檢驗方法、檢驗範圍及檢驗結果，不得有虛偽不實之情事。

五、同一份檢驗報告有非認證範圍，包括檢驗項目、檢驗方法及檢驗範圍者

Chapter 3 Management of Certification and Inspection Bodies

Article 10

When a change occurs in the matters specified in Items 1 to 3 of Paragraph 1, Article 8, the inspection body shall apply for the change to the central competent authority within the periods specified below:

1. Change of laboratory address: within thirty days from the date of occurrence.

2. Change of basis for inspection methods: within ninety days from the date of occurrence.

3. Change in inspection scope due to amendments to specific specifications and performance of medical devices: within ninety days from the effective date.

4. Change in the name of the inspection body, laboratory name, person in charge of the laboratory, or person signing the report: within ninety days from the date of occurrence.

For the application referred to in the preceding paragraph, the central competent authority may, if necessary, conduct on-site verification.

Article 11

For a change of address due to relocation as specified in Item 1, Paragraph 1 of the preceding Article, a relocation plan shall be submitted to the central competent authority fifteen days prior to the relocation.

The aforementioned plan shall include the following items:

1. The schedule of the relocation.

2. The new laboratory address and a schematic map of the location.

3. A list of inspection instruments and a layout diagram of the inspection facilities.

Article 12

If an inspection body’s dedicated laboratory is unable to perform inspections in accordance with the certified content due to any reason, it shall notify the central competent authority within seven days from the date of occurrence; the same applies when operations are resumed.

Article 13

The inspection body shall conduct inspections in accordance with the quality manual specified in Subparagraph 1 of Item 3, Article 4, and the standard operating procedures for inspection methods specified in Subparagraph 2, and shall comply with the following provisions:

1. When accepting a commissioned inspection, enter into a written inspection commission contract with the client, clearly stating the commissioned inspection items, inspection methods, inspection scope, certification status of the commissioned inspection items, and other matters. If there are any changes to the commissioned items, specify the changes and reasons in the inspection commission contract, confirmed and recorded by both parties.

2. Accurately record the client’s data and the purpose of the inspection report.

3. Accurately record the condition of received samples, including product name, batch number, manufacturing or expiry date, source, packaging, and quantity information, without leaving any fields blank, and take and retain photographs of the samples submitted for inspection.

4. The inspection report shall specify sample information, inspection items, inspection methods, inspection scope, and inspection results, and shall not contain any falsehoods or misrepresentations.

5. If an inspection report contains items or methods beyond the scope of certification, including inspection items, inspection methods, and inspection scope,

Translated by RegDesk AI

，明確載明或註記。

六、不得以非認證之檢驗方法執行認證檢驗項目之檢驗。但檢驗委託契約另有約定或委託者以書面要求，且於檢驗報告中確實敘明者，不在此限。

七、檢驗報告註明：「檢驗報告僅就委託者之委託事項提供檢驗結果，不對產品合法性作判斷」。

八、檢驗報告與品質管制資料、原始數據及其他相關紀錄，併案保存至少三年。

九、檢驗報告有防偽設計。

十、非經委託者同意，不得將受託事項轉由他人辦理；其經同意轉由他人辦理者，該他人應具執行轉委託項目之能力，且於檢驗報告中載明轉委託承接機構出具之檢驗報告編號或其他可供追溯之資料。

十一、不同產品品名、原料來源或最小獨立包裝之樣品，分別執行檢驗並出具報告，不得混測。

十二、同一樣品於一份檢驗委託契約上載明之所有委託檢驗項目，其檢驗結果以同一份檢驗報告出具。

十三、執行認證檢驗項目之檢驗，以中央主管機關認證之檢驗報告格式出具檢驗結果。

第14條

中央主管機關應定期對檢驗機構之設備、人員編組、品質管理、作業程序、檢驗能力及檢驗紀錄，進行查核，並得要求其就認證範圍之檢驗業務提出報告；必要時，得進行不定期查核。

中央主管機關得命檢驗機構參加中央主管機關自行、委託或其他經中央主管機關認可機構辦理之能力試驗；其參加費用，由檢驗機構自行負擔。

檢驗機構對於前二項之查核、提出報告及參加能力試驗之要求，不得規避、妨礙或拒絕。

第15條

檢驗機構參加前條第二項能力試驗，經評定未通過者，應自收受測試評定通知之日起十五日內完成改善，並將改善報告送中央主管機關，並於中央主管機關指定之日期，再參加能力試驗之複測。

第16條

醫療器材重大突發事件發生時，檢驗機構應依中央主管機關緊急動員之通知，於指定期限內辦理醫療器材檢驗，並將完整之樣品資訊及檢驗結果，通報中央主管機關。

6. Certified inspection items shall not be tested using non-certified testing methods. However, this shall not apply where the inspection entrustment contract stipulates otherwise, or the client makes a written request, which is clearly stated in the inspection report.

7. The inspection report shall include the following statement: “The inspection report provides the inspection results only for the matters entrusted by the client and does not make any determination regarding the legality of the product.”

8. Inspection reports, quality control data, original data, and other relevant records shall be preserved together for at least three years.

9. Inspection reports shall have anti-counterfeit design features.

10. Except with the consent of the client, entrusted matters shall not be transferred to others for handling. Where consent is given for transfer, such transferee shall possess the capacity to execute the subcontracted items, and the inspection report shall specify the report number or other traceable information from the subcontracted agency’s inspection report.

11. Samples with different product names, sources of raw materials, or minimum independent packaging shall be inspected separately and separate reports issued; combined testing is not permitted.

12. For all inspection items entrusted in a single inspection entrustment contract for the same sample, the inspection results shall be issued in a single inspection report.

13. Inspection results for certified inspection items shall be issued in the inspection report format certified by the central competent authority.

Article 14

The central competent authority shall periodically audit the inspection bodies’ equipment, personnel organization, quality management, operating procedures, inspection capabilities, and inspection records, and may require them to submit reports regarding inspection operations within the scope of certification. When necessary, unscheduled audits may be conducted.

The central competent authority may instruct inspection bodies to participate in proficiency testing conducted by the central competent authority itself, by entities commissioned by it, or by other organizations recognized by the central competent authority; the costs of participation shall be borne by the inspection body.

Inspection bodies shall not evade, obstruct, or refuse audits, requirements for report submission, or participation in proficiency testing as specified in the preceding two paragraphs.

Article 15

If an inspection body participating in the proficiency test under Paragraph 2 of the preceding article is assessed as not having passed, it shall complete corrective actions within fifteen days from the date of receiving the test assessment notification and submit a corrective action report to the central competent authority and participate in a re-test of the proficiency testing on the date specified by the central competent authority.

Article 16

In the event of a major and sudden medical device incident, the inspection body shall, in accordance with emergency mobilization notifications issued by the central competent authority, conduct medical device inspections within the designated period and report complete sample information and inspection results to the central competent authority.

Translated by RegDesk AI

第17條

檢驗機構有下列各款情事之一者，中央主管機關得暫停或廢止其認證；經廢止認證者，一年內不得重新申請認證：

一、違反第十四條第三項不得規避、妨礙或拒絕之規定。

二、檢驗數據、檢驗報告或其他提報文件、資料虛偽不實。

三、其他違反本辦法規定，經中央主管機關認定不適執行檢驗業務。

第18條

檢驗機構有下列各款情事之一者，中央主管機關得暫停或廢止其一部或全部認證項目：

一、依本辦法取得認證後，專屬實驗室不再存續或該實驗室不符合第三條所定條件。

二、違反第十條規定，未辦理變更或未於期限內辦理變更。

三、違反第十一條或第十二條規定，未於期限內提報或通知。

四、違反第十三條各款之一規定。

五、違反第十五條規定，未於期限內送交改善報告、未於指定日期參加複測或未通過複測。

六、檢驗機構停業或歇業。

第四章　委託辦理認證工作之程序

第19條

中央主管機關依本法第七十八條第二項規定，將認證工作委託其他機關（構）、法人或團體（以下簡稱受託者）辦理時，應以公開甄選方式為之。

第20條

受託者應符合下列條件：

一、具備辦理檢驗機構認證所需之經驗，並能提出證明者。

二、聘有符合下列資格之人員：

（一）國內大專校院，或符合大學、專科學校辦理國外學歷採認相關法規規定之國外大專校院以上食品、營養、生物醫學工程、醫藥、化學、生物、生命科學或其他相關科、系、所畢業，並具有從事檢驗機構檢驗能力確認之經驗。

（二）修習國內大學開設之民事、刑事及行政法規課程總計十五個學分以上，並領有學分證明。

三、其他經中央主管機關公告之條件。

151

Article 17

If a testing organization is found to have committed any of the following acts, the central competent authority may suspend or revoke its certification; where certification is revoked, the organization may not reapply for certification within one year:

1. Violation of Article 14, Paragraph 3 regarding the prohibition against evasion, obstruction, or refusal.

2. Submission of false or inaccurate testing data, test reports, or other submitted documents or information.

3. Any other violations of these Regulations as determined by the central competent authority to render the organization unsuitable for conducting testing operations.

Article 18

If a testing organization is found to have committed any of the following acts, the central competent authority may suspend or revoke part or all of its certified items:

1. After obtaining certification in accordance with these Regulations, the dedicated laboratory no longer exists or the laboratory fails to meet the conditions stipulated in Article 3.

2. Violation of Article 10 by failing to process changes or failing to do so within the specified time period.

3. Violation of Articles 11 or 12 by failing to submit reports or notifications within the deadline.

4. Violation of any of the provisions set forth in Article 13.

5. Violation of Article 15 by failing to submit an improvement report within the time limit, failing to participate in a re-inspection on the designated date, or failing to pass the re-inspection.

6. The testing organization suspends its business operations or ceases operations.

Chapter 4 Procedure for the Entrustment of Certification Work

Article 19

Pursuant to Article 78, Paragraph 2 of the Act, when the central competent authority entrusts certification work to other agencies (institutions), legal persons, or groups (hereafter referred to as “the entrusted party”), it shall do so through a public selection process.

Article 20

The entrusted party shall meet the following conditions:

1. Possess the necessary experience for conducting certification of testing organizations and be able to provide proof thereof.

2. Employ personnel with the following qualifications:

(1) Graduated from domestic universities or colleges, or from overseas universities or colleges that comply with domestic regulations regarding the recognition of foreign academic credentials, with a major in food, nutrition, biomedical engineering, medicine, chemistry, biology, life science, or other related departments or institutes, and have experience in conducting competency assessments for testing organizations.

(2) Have completed a total of at least 15 credits of civil, criminal, and administrative law courses offered by domestic universities and hold proof of credit.

3. Other conditions as announced by the central competent authority.

Translated by RegDesk AI

第五章　受託認證機構之管理

第21條

受託者應建置管理系統，配合其執行之認證工作內容建立相關程序，並編製成手冊；其內容包括下列事項：

一、組織架構。

二、文件管制。

三、紀錄。

四、不符合事項及矯正措施。

五、預防措施。

六、內部稽核。

七、管理審查。

八、抱怨。

前項手冊，受託者應定期審查其適用性，並因應實際需要隨時更新或修正。

第一項第六款、第七款事項，受託者應每年至少執行一次。

第22條

受託者應確保其執行認證人員具備醫療器材檢驗相關知識及能力，並備有受託者對該人員初次及定期評估之紀錄。

前項人員，每年應接受中央主管機關認可之機關（構）或民間機構、團體辦理之繼續教育訓練十二小時以上；其課程包括查核技巧、檢驗知能及相關法令。

第23條

受託者於辦理認證工作時所獲得之資料及檢驗機構提供之認證資料，應至少保存十五年；與認證工作相關之各項文件、資料，應永久保存。

受託者於委託關係終止時，應將前項保存之文件、資料，交付予中央主管機關。

第24條

受託者對於執行認證工作所獲得之資訊，應負保密義務，不得無故洩漏。

第25條

受託者依第六條第一項進行實地查核時，應於查核一星期前，將預定行程通知中央主管機關；中央主管機關得派員隨同查核，受託者不得規避、妨礙或拒絕。

Chapter 5: Management of Designated Certification Bodies

Article 21

The designated party shall establish a management system and develop relevant procedures corresponding to the certification tasks performed, to be compiled into a manual. The content shall include the following items:

1. Organizational structure.

2. Document control.

3. Records.

4. Non-conformities and corrective actions.

5. Preventive measures.

6. Internal audits.

7. Management review.

8. Complaints.

The manual mentioned in the preceding paragraph shall be periodically reviewed by the designated party for its applicability and be updated or revised at any time as necessary.

Regarding the items specified in Subparagraphs 6 and 7 of Paragraph 1, the designated party shall conduct them at least once a year.

Article 22

The designated party shall ensure that the personnel performing certification possess relevant knowledge and competencies in medical device inspection, and shall keep records of the initial and periodic evaluations of said personnel.

The personnel mentioned in the preceding paragraph shall annually receive more than 12 hours of continuing education training organized by agencies (institutions) or private organizations/groups recognized by the central competent authority; the training courses shall include auditing skills, inspection expertise, and relevant regulations.

Article 23

The information obtained by the designated party during certification activities and the certification data provided by the inspection body shall be retained for at least fifteen years; all documents and information related to certification activities shall be permanently preserved.

Upon termination of the contractual relationship, the designated party shall transfer the documents and data retained in the preceding paragraph to the central competent authority.

Article 24

The designated party shall be obliged to maintain the confidentiality of information obtained through certification activities and shall not disclose it without valid reason.

Article 25

When the designated party conducts on-site audits in accordance with Paragraph 1 of Article 6, it shall notify the central competent authority of the scheduled itinerary one week prior to the audit; the central competent authority may assign personnel to accompany the audit. The designated party shall not evade, obstruct, or refuse such accompaniment.

Translated by RegDesk AI

第26條

受託者應逐案將認證結果通知中央主管機關，並檢附相關文件、資料。

第27條

中央主管機關得通知受託者提供業務文件、資料，並至受託者營業場所進行不定期查核。

受託者對於前項通知、提供或查核，不得規避、妨礙或拒絕。

第28條

受託者依本辦法規定應提供中央主管機關之文件、資料，不得虛偽不實。

第29條

受託者及其人員受託辦理認證工作時，其迴避事項，依行政程序法之規定。

受託者辦理前項工作時，不得有觸犯刑事法律之行為；有觸犯嫌疑者，中央主管機關應將其移送司法機關偵辦。

第30條

中央主管機關應與受託者訂定委託契約書，載明委託項目與內容、相關權利義務、違約處罰事由、爭議處理機制、暫停與終止委託事由及其他事項。

第31條

受託者有下列各款情事之一者，中央主管機關得暫停或終止其委託；其情節重大並經終止委託者，一年內不得再接受委託：

一、違反第二十四條規定。

二、違反第二十五條規定，未依期限通知中央主管機關，或規避、妨礙或拒絕中央主管機關之隨同查核。

三、違反第二十七條第二項規定。

四、違反第二十八條規定。

五、違反第二十九條第一項迴避規定。

六、有第二十九條第二項觸犯刑事法律情形。

第六章　附則

第32條

本辦法自中華民國一百十年五月一日施行。

Article 26

The entrusted party shall notify the central competent authority of the certification results on a case-by-case basis and attach relevant documents and materials.

Article 27

The central competent authority may notify the entrusted party to provide business documents and materials, and may conduct unscheduled inspections at the business premises of the entrusted party.

The entrusted party shall not evade, obstruct, or refuse the aforementioned notifications, provisions, or inspections.

Article 28

Documents and materials that the entrusted party is required to provide to the central competent authority in accordance with these Regulations shall not be false or untrue.

Article 29

The recusal matters concerning the entrusted party and its personnel when undertaking certification work shall be handled in accordance with the provisions of the Administrative Procedure Act.

When handling the aforementioned work, the entrusted party shall not engage in acts that violate criminal laws; if there is suspicion of such violation, the central competent authority shall refer the case to judicial authorities for investigation.

Article 30

The central competent authority shall enter into an entrustment contract with the entrusted party, specifying the entrusted items and contents, related rights and obligations, causes for penalties for breaches, dispute resolution mechanisms, causes for suspension or termination of entrustment, and other matters.

Article 31

If the entrusted party is found to have any of the following circumstances, the central competent authority may suspend or terminate their entrustment; if the violation is serious and the entrustment is terminated, the entrusted party shall not be eligible for further entrustment within one year:

1. Violation of the provisions of Article 24.

2. Violation of the provisions of Article 25, failure to notify the central competent authority within the prescribed period, or evasion, obstruction, or refusal of inspection conducted by the central competent authority.

3. Violation of Article 27, Paragraph 2.

4. Violation of Article 28.

5. Violation of the recusal provisions of Article 29, Paragraph 1.

6. Circumstances as described in Article 29, Paragraph 2 regarding the commission of criminal offences.

Chapter 6 Supplementary Provisions

Article 32

These Regulations shall enter into force on May 1, 2021.

Translated by RegDesk AI

【醫療器材管理事項委託及受託機構認證作業辦法】(110.04.29發布)

第一章　總則

第1條

本辦法依醫療器材管理法（以下簡稱本法）第七十九條第二項規定訂定之。

第2條

本辦法用詞，定義如下：

一、受託機構：指受主管機關委託辦理本法第七十九條第一項事項之機關（構）、法人或團體。

二、認證：指主管機關對法人或團體，確認其有能力執行本法第七十九條第一項事項之處分。

第3條

中央主管機關依本法第七十九條第一項規定，委託其他機關（構）辦理技術人員教育訓練及醫療器材商檢查事項時，雙方之權利、義務，應以行政契約定之。

中央主管機關依本法第七十九條第一項規定，委託法人或團體辦理前項受託事項時，應按個別受託事項，由法人或團體依本辦法規定申請認證。

第二章　醫療器材技術人員教育訓練之認證及管理

第4條

法人或團體受託辦理技術人員教育訓練前，應填具申請書，並檢附下列文件、資料，向中央主管機關申請認證：

一、依法立案或登記滿三年之證明文件。

二、勞動部勞動力發展署人才發展品質管理系統（TTQS），就辦理訓練品質及績效，評核達「通過」等級以上或「合格」之證明文件、資料。

前項申請文件、資料有不完備，其得補正者，中央主管機關應通知申請人限期補正；屆期未補正者，予以駁回。

第一項申請，經審查通過及核定後，由中央主管機關發給認證證明文件及委託同意書。

前項認證證明文件，應載明下列事項：

一、法人或團體名稱及地址。

二、認證範圍。

三、認證有效期間。

154

Regulations for Delegation of Medical Device Management Matters and Certification Operations for Entrusted Institutions (Promulgated 2021.04.29)

Chapter 1 General Provisions

Article 1

These Regulations are established in accordance with Paragraph 2, Article 79 of the Medical Devices Act (hereinafter referred to as “the Act”).

Article 2

The terms used in these Regulations are defined as follows:

1. Entrusted Institution: Refers to an agency (institution), legal person, or group entrusted by the competent authority to handle the matters specified in Paragraph 1, Article 79 of the Act.

2. Certification: Refers to the disposition whereby the competent authority confirms that a legal person or group is capable of performing the matters specified in Paragraph 1, Article 79 of the Act.

Article 3

When the central competent authority, in accordance with Paragraph 1, Article 79 of the Act, entrusts another agency (institution) to handle education and training for technical personnel or the inspection of medical device businesses, the respective rights and obligations of both parties shall be stipulated by an administrative contract.

When the central competent authority, in accordance with Paragraph 1, Article 79 of the Act, entrusts a legal person or group to handle the aforementioned entrusted matters, such legal person or group shall apply for certification for each entrusted matter in accordance with the provisions of these Regulations.

Chapter 2 Certification and Management of Education and Training for Medical Device Technical Personnel

Article 4

Prior to being entrusted to handle technical personnel education and training, a legal person or group shall fill out an application form and submit the following documents and information to the central competent authority for certification:

1. Documentary proof of legal establishment or registration for at least three years in accordance with the law.

2. Documentary proof or information showing that the Labor Development Quality Management System (TTQS) of the Workforce Development Agency, Ministry of Labor, has evaluated the quality and performance of training to reach a rating of "Pass" or above, or "Qualified".

If the application documents or information mentioned in the preceding paragraph are incomplete but may be rectified, the central competent authority shall notify the applicant to supplement or rectify within a specified time period; if the applicant fails to supplement or rectify within the period, the application shall be rejected.

Upon passing the review and approval of the application under Paragraph 1, the central competent authority shall issue a certification document and a letter of consent for entrustment.

The certification document mentioned in the preceding paragraph shall specify the following matters:

1. Name and address of the legal person or group.

2. Scope of certification.

Translated by RegDesk AI

3. Validity period of certification.

Translated by RegDesk AI

第5條

受託機構辦理技術人員教育訓練，其訓練課程項目，應符合醫療器材技術人員管理辦法第五條及第十一條規定。

受託機構應於每次教育訓練課程結束之次日起七日內，將參加訓練人員之姓名、國民身分證統一編號或身分證明文件號碼、課程項目及時數，上傳至中央主管機關指定之資訊系統。

受託機構執行前二項委託事項之相關文件、資料，應保存三年；其涉及個人資料者，應依個人資料保護法相關規定辦理。

第6條

中央主管機關得就受託機構辦理教育訓練之內容及其他相關事項，進行不定期查核；受託機構不得規避、妨礙或拒絕。

受託機構以虛偽不實文件、資料或其他不正當方法取得認證者，中央主管機關得撤銷之，並終止委託訓練行政契約。

受託機構有下列情形之一者，中央主管機關應通知其限期改善；屆期不改善者，得廢止其認證，並終止委託訓練行政契約：

一、受託辦理訓練課程項目，違反前條第一項規定。

二、未依前條第二項規定之期限、內容或方式上傳資料，或上傳之資料虛偽不實。

三、違反第一項規定，規避、妨礙或拒絕中央主管機關之查核。

第三章　醫療器材商檢查之認證及管理

第7條

本辦法所定醫療器材商檢查之範圍如下：

一、本法第二十二條醫療器材品質管理系統相關事項。

二、本法第二十四條醫療器材優良運銷系統相關事項。

第8條

法人或團體受託辦理醫療器材商檢查，應具備下列要件：

一、置有專職之檢查人員至少三人。

二、訂有檢查作業及檢查人員管理之相關程序、規範。

三、其他經中央主管機關指定之事項。

第9條

法人或團體申請醫療器材商檢查之認證，應填具申請書，並檢附下列文件、資料，向中央主管機關提出：

Article 5

When an entrusted institution conducts training for technical personnel, the training course items shall comply with the provisions of Articles 5 and 11 of the Regulations on the Management of Medical Device Technical Personnel.

The entrusted institution shall, within seven days from the day following the conclusion of each educational training course, upload the names of the training participants, their National Identification Number or identification document number, course items, and training hours to the information system designated by the central competent authority.

The relevant documents and materials related to the entrusted tasks specified in the preceding two paragraphs executed by the entrusted institution shall be retained for three years; those involving personal data shall be handled in accordance with relevant provisions of the Personal Data Protection Act.

Article 6

The central competent authority may conduct unscheduled audits regarding the content and other related matters of educational training conducted by the entrusted institution; the entrusted institution must not evade, obstruct, or refuse such audits.

If the entrusted institution obtains certification through false or untruthful documents, data, or other improper means, the central competent authority may revoke such certification and terminate the administrative contract for entrusted training.

If any of the following situations apply to the entrusted institution, the central competent authority shall notify it to make improvements within a specified period; if improvements are not made upon expiration of the period, the authority may revoke its certification and terminate the administrative contract for entrusted training:

1. In contravention of the provisions of Paragraph 1 of the preceding article regarding the items of training courses conducted under the entrustment.

2. Failure to upload information within the time limit, content, or method specified in Paragraph 2 of the preceding article, or uploading of false or untruthful information.

3. Violation of the provisions in Paragraph 1 by evading, obstructing, or refusing audits by the central competent authority.

Chapter 3 Certification and Management of Medical Device Dealer Inspections

Article 7

The scope of medical device dealer inspections stipulated in these Regulations is as follows:

1. Matters related to the medical device quality management system under Article 22 of this Act.

2. Matters related to the medical device Good Distribution Practice (GDP) system under Article 24 of this Act.

Article 8

A legal entity or organization entrusted to conduct medical device dealer inspections shall meet the following requirements:

1. Employ at least three full-time inspectors.

2. Establish relevant procedures and regulations for inspection operations and inspector management.

3. Other matters designated by the central competent authority.

Article 9

Translated by RegDesk AI

A legal entity or organization applying for certification to conduct medical device dealer inspections shall complete an application form and submit the following documents and materials to the central competent authority:

Translated by RegDesk AI

一、依法立案或登記之證明文件。

二、符合前條各款要件之證明文件、資料。

三、組織簡介、組織架構、負責人、部門主管、檢查人員、業務概要、檢查品質管理能力及作業程序說明。

四、董（理）事、監察人（監事）、負責人、執行長（或相當該等職務之人）及簽署檢查報告人員之名冊。

五、其他經中央主管機關指定之文件、資料。

前項申請文件、資料有不完備，其得補正者，中央主管機關應通知申請人限期補正；屆期未補正者，予以駁回。

第10條

中央主管機關受理前條申請，應進行現場查核，必要時，得聘請技術專家參與。

前項查核，應製作紀錄；發現有缺失者，應將缺失紀錄及改善期限通知申請人。

申請人應於前項期限內，將改善報告送中央主管機關；屆期未改善或未送改善報告者，予以駁回。

第11條

經前條查核通過者，由中央主管機關發給認證證明文件及委託同意書。

前項認證證明文件，應載明下列事項：

一、法人或團體名稱及地址。

二、負責人姓名。

三、認證範圍。

四、認證編號。

五、認證有效期間。

六、其他經中央主管機關指定之事項。

第12條

前條認證有效期間為三年；有展延必要者，應於期滿六個月前至十二個月間申請展延，展延期間最長為三年；其申請及認證程序，得準用第七條至前條規定。

第13條

法人或團體取得第十一條第一項認證證明文件及委託同意書之次日起一年內，應與中央主管機關簽訂行政契約，並於行政契約簽訂後，始得辦理受託事項。

156

1. Documentary evidence for legal establishment or registration.

2. Documentary evidence and information demonstrating compliance with all the requirements listed in the preceding Article.

3. An introduction of the organization, organizational structure, details of responsible person(s), department heads, inspectors, summary of business operations, explanation of inspection quality management capability and operational procedures.

4. Rosters of directors (or council members), supervisors (or supervisory board members), responsible person(s), CEO (or persons holding equivalent titles), and personnel who sign inspection reports.

5. Other documents or information as designated by the central competent authority.

If the application documents or materials submitted in accordance with the preceding paragraph are incomplete and are eligible for supplementation, the central competent authority shall notify the applicant to make corrections within a specified time limit; if corrections are not made by the deadline, the application shall be rejected.

Article 10

Upon accepting the application under the preceding Article, the central competent authority shall conduct an on-site audit, and when necessary, may engage technical experts to participate.

A record shall be made of the audit conducted under the preceding paragraph; if deficiencies are found, the deficiencies and the deadline for correction shall be notified to the applicant.

The applicant shall submit a corrective action report to the central competent authority within the specified deadline in the preceding paragraph; if corrections are not made or the corrective action report is not submitted by the deadline, the application shall be rejected.

Article 11

Applicants who pass the audit under the preceding Article shall be issued a certification document and a letter of commissioning consent by the central competent authority.

The certification document referred to in the preceding paragraph shall specify the following matters:

1. Name and address of the juridical person or organization.

2. Name of the responsible person.

3. Scope of certification.

4. Certification number.

5. Validity period of the certification.

6. Other matters as designated by the central competent authority.

Article 12

The validity period of the certification in the preceding Article is three years; if an extension is necessary, the application for extension must be submitted six to twelve months before expiration, and the maximum extension period is three years; the application and certification procedures may be conducted in accordance with the provisions of Articles 7 through the preceding Article.

Article 13

Translated by RegDesk AI

Within one year after obtaining the certification document and the letter of commissioning consent as set forth in Paragraph 1 of Article 11, the juridical person or organization shall execute an administrative contract with the central competent authority, and may only begin to carry out the commissioned matters after the execution of the administrative contract.

Translated by RegDesk AI

申請人未依前項規定簽訂行政契約者，中央主管機關得廢止其認證。

第14條

第十一條第二項第一款或第二款事項有變更時，法人或團體應檢附相關文件、資料，向中央主管機關申請變更。

第九條第一項第二款至第四款事項有變更時，法人或團體應檢附相關文件、資料，報中央主管機關備查。

前二項申請或報請備查，受託機構應自事實發生之次日起三十日內為之。

第15條

中央主管機關得於法人或團體辦理受託事項期間，進行定期或不定期查核，該法人或團體不得規避、妨礙或拒絕。

前項查核，應製作紀錄；發現有缺失者，中央主管機關應將缺失紀錄及改善期限，通知該法人或團體；法人或團體應於期限內，將改善報告送中央主管機關。

第16條

受託機構辦理醫療器材商檢查時，其檢查及簽署檢查報告之人員就其檢查案件，有行政程序法第三十二條、第三十三條或下列各款情形之一者，應自行迴避：

一、為受檢查所涉醫療器材之設計者、製造者、供應者、安裝者、購入或承租者、所有者或維修管理者，或其受雇人或代理人。但為個人用途、受託機構運作或為檢查必要之購入，不在此限。

二、五年內曾參與受檢查所涉醫療器材之設計、製造、組裝、市場規劃、安裝操作或維修之從業人員。

三、現為或曾為受檢查醫療器材商之從業人員。

四、現為受檢查醫療器材商諮詢輔導機構之從業人員。

第17條

受託機構有下列情形之一者，應通知中央主管機關：

一、受託機構之檢查及簽署檢查報告之人員，有前條應迴避之情事。

二、有嚴重影響檢查獨立性、公正性或有影響之虞。

中央主管機關得依前項通知，變更受託機構。

第一項受託機構變更時，原受託機構應將已取得受檢查醫療器材商之文件、資料，移交予變更後之受託機構。

157

If an applicant fails to enter into an administrative contract in accordance with the preceding paragraph, the central competent authority may revoke their certification.

Article 14

When there is a change in the matters specified in Subparagraph 1 or 2 of Paragraph 2, Article 11, the legal person or organization shall attach relevant documents and materials to apply to the central competent authority for change.

When there is a change in the matters specified in Subparagraphs 2 to 4 of Paragraph 1, Article 9, the legal person or organization shall attach relevant documents and materials and report to the central competent authority for recordation.

For the applications or reporting for recordation specified in the preceding two paragraphs, the entrusted institution shall complete the process within thirty days from the day following the occurrence of the fact.

Article 15

The central competent authority may conduct periodic or non-periodic inspections on the matters entrusted to the legal person or organization; such legal person or organization must not evade, obstruct, or refuse such inspections.

Records shall be made of the inspections in the preceding paragraph. If deficiencies are found, the central competent authority shall notify the legal person or organization by providing a record of the deficiencies and a deadline for rectification; the legal person or organization shall submit an improvement report to the central competent authority within the specified period.

Article 16

When the entrusted institution conducts inspections of medical device suppliers, the personnel responsible for the inspection and signing of the inspection report, if subject to the circumstances outlined in Articles 32 or 33 of the Administrative Procedure Act or any of the following subparagraphs regarding their inspection cases, shall recuse themselves:

1. Is the designer, manufacturer, supplier, installer, buyer, lessee, owner, or maintenance manager of the medical device under inspection, or an employee or agent thereof. However, purchases for personal use, institution operation, or inspection necessity are not subject to this restriction.

2. Has, within the past five years, participated as a practitioner in the design, manufacture, assembly, marketing, installation, operation, or maintenance of the medical device under inspection.

3. Is currently or has previously been an employee of the inspected medical device supplier.

4. Is currently an employee of a consulting or advisory institution for the inspected medical device supplier.

Article 17

If the entrusted institution encounters any of the following situations, it shall notify the central competent authority:

1. Any personnel responsible for inspection and signing of inspection reports are subject to recusals described in the preceding article.

2. There is a serious impact, or risk of impact, on the independence or impartiality of the inspection.

The central competent authority may, upon receiving notification under the preceding paragraph, change the entrusted institution.

Translated by RegDesk AI

When the entrusted institution is changed pursuant to Paragraph 1, the original entrusted institution shall transfer the documents and materials already obtained from the inspected medical device supplier to the new entrusted institution.

Translated by RegDesk AI

第18條

受託機構應訂定及執行檢查人員訓練計畫，並記錄各人員之訓練時數及考核結果。

前項訓練計畫之內容，應按認證範圍，載明下列事項：

一、醫療器材品質管理系統準則內容及其檢查實務。

二、醫療器材優良運銷準則內容及其檢查實務。

中央主管機關於必要時，應於行政契約明定受託機構辦理檢查及簽署檢查報告人員之能力管理規定。

第19條

受託機構辦理檢查工作，應遵行下列事項：

一、對於執行工作所取得之資訊，應予保密，不得無故洩漏。

二、不得行求、期約或收受賄賂或其他不正利益。

三、檢查結果及其紀錄，不得有偽造、變造或登載不實之情事。

四、不得將全部或部分檢查業務，再委託或移轉至其他法人、團體或機構辦理。

五、配合中央主管機關之調查，或受理有關檢查之查詢、申覆或陳情，提供相關文件、資料、紀錄及說明。

六、受檢廠商提供及受託機構檢查所生之文件、資料及紀錄，至少保存六年。

第20條

經認證之法人或團體有下列情形之一者，中央主管機關得撤銷或廢止第十一條之認證：

一、以虛偽不實文件、資料或其他不正當方法取得認證。

二、違反前條第一款至第五款規定之一。

三、違反第十五條第一項規定，規避、妨礙或拒絕中央主管機關之檢查。

四、違反第十五條第二項規定，屆期未改善或未送改善報告至中央主管機關。

五、檢查及簽署檢查報告之人員，未依第十六條規定自行迴避。

六、違反第十七條第一項規定，未通知中央主管機關，或違反同條第三項規定，未移交文件、資料。

七、其他違反委託事項、行政契約或法規規定，經中央主管機關認定影響檢查工作，且情節重大。

Article 18

The entrusted organization shall formulate and implement a training plan for inspection personnel, and record the training hours and assessment results for each personnel member.

The content of the training plan in the preceding paragraph shall, according to the scope of certification, specify the following matters:

1. Content of the Medical Device Quality Management System Guidelines and related inspection practices.

2. Content of the Medical Device Good Distribution Practice Guidelines and related inspection practices.

When necessary, the central competent authority shall specify in the administrative contract the competency management regulations for personnel of the entrusted organization who conduct inspections and sign inspection reports.

Article 19

When conducting inspection work, the entrusted organization shall comply with the following provisions:

1. Information obtained during the execution of duties shall be kept confidential and shall not be disclosed without legitimate reason.

2. Shall not solicit, agree to receive, or accept bribes or other undue benefits.

3. Inspection results and relevant records shall not be falsified, altered, or contain false information.

4. The entire or part of the inspection business shall not be subcontracted or transferred to other legal persons, groups, or organizations.

5. Cooperate with investigations by the central competent authority, or when handling inquiries, appeals, or complaints related to inspections, provide relevant documents, data, records, and explanations.

6. Documents, data, and records provided by the inspected manufacturer and generated by the entrusted organization during inspection shall be preserved for at least six years.

Article 20

For any of the following circumstances regarding a certified legal person or group, the central competent authority may revoke or annul the certification under Article 11:

1. Obtaining certification by means of false or untruthful documents, data, or other improper methods.

2. Violation of any provision from Subparagraphs 1 to 5 of the preceding article.

3. Violation of Paragraph 1, Article 15, namely, evasion, obstruction, or refusal of inspection by the central competent authority.

4. Violation of Paragraph 2, Article 15, namely, failure to make improvements or failure to submit an improvement report to the central competent authority within the specified period.

5. Failure of personnel responsible for inspections and for signing inspection reports to recuse themselves in accordance with Article 16.

6. Violation of Paragraph 1, Article 17—failure to notify the central competent authority, or violation of Paragraph 3 of the same article—failure to transfer documents and data.

Translated by RegDesk AI

7. Any other violation of the entrusted matters, administrative contract, or legal regulations, as determined by the central competent authority to significantly affect inspection work and where the circumstances are serious.

Translated by RegDesk AI

第21條

經認證之法人或團體有下列情形之一，經中央主管機關令其限期改善，屆期未改善者，得停止其全部或部分檢查業務；其情節重大者，中央主管機關得廢止其認證：

一、未具備第八條規定之要件。

二、未依第十九條第六款規定保存文件、資料或紀錄。

三、檢查業務之品質或效率不佳。

四、其他違反委託事項、行政契約或法規規定，經中央主管機關認定影響檢查工作。

第22條

法人或團體經撤銷或廢止認證者，中央主管機關應令其停止受託檢查事項之執行，並終止檢查行政契約。

前項情形，法人或團體應將已完成及辦理中檢查案件之文件、資料及紀錄，返還中央主管機關；認證展延未通過者，亦同。

第四章　附則

第23條

本辦法自中華民國一百十年五月一日施行。

Article 21

If a certified legal entity or organization falls under any of the following circumstances, the central competent authority may order it to make improvements within a prescribed period; if it fails to make improvements within the given period, the central competent authority may suspend all or part of its inspection operations. If the circumstances are severe, the central competent authority may revoke its certification:

1. Failure to meet the requirements stipulated in Article 8.

2. Failure to retain documents, data, or records as stipulated in Subparagraph 6, Article 19.

3. Poor quality or efficiency in inspection operations.

4. Other violations of entrusted matters, administrative contracts, or legal provisions that, as determined by the central competent authority, affect inspection work.

Article 22

If a legal entity or organization has its certification revoked or abolished, the central competent authority shall order it to cease handling entrusted inspection matters and shall terminate the inspection administrative contract.

In the circumstances mentioned in the preceding paragraph, the legal entity or organization shall return all documents, data, and records of completed and ongoing inspection cases to the central competent authority; the same shall apply in the event that the extension of certification is not approved.

Chapter 4 Supplemental Provisions

Article 23

These Regulations shall come into force on May 1, 2021.

Translated by RegDesk AI

【醫療器材創新科技研究發展獎勵辦法】(110.04.29發布)

第1條

本辦法依醫療器材管理法第八十條第二項規定訂定之。

第2條

本辦法獎勵對象，為我國醫療器材商，及我國其他從事醫療器材創新科技研究發展之自然人、機構、學校、法人或團體。

第3條

前條獎勵對象，應具備下列條件之一：

一、取得國內、外發明專利或專利授權，且獲得我國或其他國家醫療器材製造或輸入許可、核准或登錄者。

二、取得國內、外發明專利或專利授權，而尚未獲得我國醫療器材製造或輸入許可或登錄，業經完成國內或國外臨床試驗研究。

三、國內製造之醫療器材，取得國內、外專利，且對醫療器材製造工業發展有顯著貢獻。

四、國內製造之醫療器材，有重要及具體之市場成效。

五、國內製造之醫療器材材質、零組件，對提升醫療器材製造工業發展有顯著貢獻。

六、國內開發之新設備、設施、裝置、製程或分析檢驗方法，對改進醫療器材之製造或檢驗技術有顯著貢獻。

七、配合中央主管機關或中央工業主管機關政策，對推動醫療器材製造工業發展，或提升醫療器材研發水準有顯著貢獻。

八、其他經中央主管機關會同中央工業主管機關認定有顯著貢獻。

第4條

申請獎勵者，應填具申請書，並檢附下列文件、資料，向中央主管機關提出：

一、前條第一款：

（一）專利權證明書、專利授權書或技術授權書。

（二）醫療器材製造或輸入許可證、核准或登錄證明。

二、前條第二款：

（一）專利權證明書、專利授權書或技術授權書。

（二）臨床試驗報告或人體試驗報告。

三、前條第三款：

（一）國內製造許可證。

（二）專利權證明書。

（三）技術說明書。

160

[Regulations for Incentives for the Research and Development of Innovative Medical Device Technologies] (Promulgated on 2021.04.29)

Article 1

These Regulations are enacted pursuant to Paragraph 2, Article 80 of the Medical Devices Act.

Article 2

The recipients of incentives under these Regulations shall be domestic medical device businesses, as well as other natural persons, institutions, schools, legal persons, or organizations in Taiwan engaged in research and development of innovative medical device technologies.

Article 3

The incentive recipients mentioned in the preceding Article must meet one of the following conditions:

1. Have obtained domestic or foreign invention patents or patent authorizations, and have also received manufacturing or import permits, approvals, or registrations for medical devices in Taiwan or other countries.

2. Have obtained domestic or foreign invention patents or patent authorizations, and, while not yet having obtained Taiwan's medical device manufacturing or import permits or registration, have completed domestic or overseas clinical trial research.

3. Medical devices manufactured domestically that have obtained domestic or foreign patents and have made significant contributions to the development of the medical device manufacturing industry.

4. Medical devices manufactured domestically which have achieved significant and concrete market success.

5. Materials or components of domestically manufactured medical devices that have made significant contributions to the development of the medical device manufacturing industry.

6. Newly developed equipment, facilities, devices, processes, or analytical testing methods in Taiwan that have made significant contributions to improving the manufacturing or testing technology of medical devices.

7. Those who, in coordination with the policies of the central competent authority or the central industrial competent authority, have made significant contributions to promoting the development of the medical device manufacturing industry or enhancing the standard of medical device research and development.

8. Other significant contributions as recognized jointly by the central competent authority and the central industrial competent authority.

Article 4

Applicants for incentives shall fill out the application form and submit the following documents and information to the central competent authority:

1. For Item 1 of the preceding Article:

(1) Patent certificate, patent authorization certificate, or technology licensing agreement.

(2) Medical device manufacturing or import permit, approval, or registration certificate.

2. For Item 2 of the preceding Article:

(1) Patent certificate, patent authorization certificate, or technology licensing agreement.

Translated by RegDesk AI

(2) Clinical trial report or human trial report.

3. For Item 3 of the preceding Article:

(1) Domestic manufacturing permit.

(2) Patent certificate.

(3) Technical description.

Translated by RegDesk AI

（四）顯著貢獻之佐證。

四、前條第四款：

（一）國內製造許可證。

（二）重要及具體市場成效之佐證。

五、前條第五款：

（一）材質、零組件之技術或產品說明書。

（二）顯著貢獻之佐證。

六、前條第六款：

（一）新設備、設施、裝置、製程或分析檢驗方法之說明。

（二）顯著貢獻之佐證。

七、前條第七款及第八款：顯著貢獻之說明及佐證。

本辦法所定獎勵，得由中央主管機關或中央工業主管機關主動推薦，並通知受推薦者依前項規定檢附相關文件、資料，向中央主管機關提出。

第5條

中央主管機關為審議前條申請或推薦案件，得組成醫療器材創新科技研究發展審議會（以下簡稱審議會）。

審議會置委員九人至十三人，由中央主管機關首長就相關學者專家與學術機構、科技或工業界、主管業務及有關機關之代表聘（派）兼之，其中一人為召集人，由首長就委員之一指定之。

審議會應有全體委員過半數之出席，始得開會；應有出席委員過半數之同意，始得決議。

審議會會議，專家學者委員應親自出席，不得代理。以機關（構）及業務代表身分擔任之委員未能親自出席時，得指派相關人員代理出席，並得參加討論及表決。

審議會委員之迴避事項，依行政程序法之規定。

第6條

本辦法獎勵方式，包括發給獎狀、獎盃（座）或獎金。

第7條

本辦法所需之獎勵經費，由下列財源籌措：

一、中央主管機關及中央工業主管機關逐年編列預算支應。

二、私人或團體指定用於本辦法獎勵之捐助。

第8條

本辦法自中華民國一百十年五月一日施行。

161

(4) Documentation of significant contributions.

4. For Item 4 of the preceding Article:

(1) Domestic manufacturing license.

(2) Evidence demonstrating significant and concrete market performance.

5. For Item 5 of the preceding Article:

(1) Technical or product specifications of materials or components.

(2) Documentation of significant contributions.

6. For Item 6 of the preceding Article:

(1) Description of new equipment, facilities, devices, processes, or analytical or inspection methods.

(2) Documentation of significant contributions.

7. For Items 7 and 8 of the preceding Article: Description and supporting documentation of significant contributions.

Awards stipulated in these Regulations may be proactively recommended by the central competent authority or the central industrial competent authority, which shall notify the recommended party to submit relevant documents and materials, as specified in the preceding paragraph, to the central competent authority.

Article 5

To review applications or recommendations as referred to in the preceding Article, the central competent authority may set up the Review Committee for Innovative Medical Device Technology Research and Development (hereinafter referred to as "the Review Committee").

The Review Committee shall comprise nine to thirteen members, who shall be appointed (assigned concurrently) by the head of the central competent authority from among relevant scholars, experts, and representatives of academic institutions, the technological or industrial sector, supervising authorities, and related agencies; one member shall serve as the convener as designated by the head from among the committee members.

More than half of all committee members must be present for the Review Committee to convene a meeting; approval by more than half of the members present is required for a resolution to be adopted.

Expert and scholar members of the Review Committee must attend meetings in person and may not appoint substitutes. Committee members representing agencies (organizations) or serving in an official capacity who are unable to attend in person may designate relevant personnel to attend as substitutes, who may participate in discussions and voting.

Recusal matters of Review Committee members shall be handled in accordance with the provisions of the Administrative Procedure Act.

Article 6

Forms of awards under these Regulations include the issuance of certificates of merit, trophies (plaques), or monetary awards.

Article 7

The funding required for the awards under these Regulations shall be sourced as follows:

Translated by RegDesk AI

1. Annual appropriations in the budgets of the central competent authority and the central industrial competent authority.

2. Donations from individuals or organizations specifically designated for the awards under these Regulations.

Article 8

These Regulations shall be implemented from May 1, 2021.

Translated by RegDesk AI

醫療器材管理法相關公告

162

Medical Devices Act – Related Announcements

Translated by RegDesk AI

目錄

發文日期	主旨
醫療器材管理法第 13 條	
110 年 4 月 28 日	訂定「醫療器材商(藥局)分設醫療器材自動販賣機免各別辦理營業處所販賣業許可執照」，並自中華民國一百十年五月一日生效
醫療器材管理法第 14 條	
110 年 3 月 30 日	訂定「藥局得兼營醫療器材零售業務之範圍及種類」，並自中華民國一百十年五月一日生效
醫療器材管理法第 18 條	
110 年 4 月 29 日	訂定「通訊交易通路販售醫療器材之品項及應遵行事項」，並自中華民國一百十年五月一日生效
110 年 6 月 25 日	訂定「得以自動販賣機販售之醫療器材種類及其販售之應遵循事項」，並自即日生效
醫療器材管理法第 19 條	
110 年 4 月 28 日	訂定「應建立與保存來源及流向資料之醫療器材」及「應申報來源及流向資料之醫療器材品項」，並自即日生效
醫療器材管理法第 22 條	
110 年 7 月 16 日	訂定「免取得醫療器材製造許可品項」，並自即日生效。
醫療器材管理法第 24 條	
110 年 3 月 18 日	訂定「醫療器材管理法第二十四條應建立醫療器材優良運銷系統之醫療器材品項及其販賣業者」，並中華民國一百十二年五月一日生效。
醫療器材管理法第 25 條	
110 年 4 月 13 日	訂定「應以登錄方式取得上市許可之醫療器材品項」，並自中華民國一百十年十月一日生效
醫療器材管理法第 30 條	
112 年 8 月 15 日	訂定「特定醫療器材品項應符合之規格、檢驗方法及性能」，並至中華民國一百十三年九月一日生效
醫療器材管理法第 33 條	
110 年 4 月 28 日	訂定「醫療器材之標籤、說明書或包裝得免刊載製造日期及有效期間，或保存期限之規定」，並自中華民國一百十年五月一日生效
110 年 6 月 1 日	修訂「特定醫療器材之標籤、說明書或包裝應加註警語及注意事項」，並自即日生效
110 年 8 月 5 日	訂定「依醫療器材管理法第二十五條第四項規定，由中央主管機關逕予登錄及註銷原許可證者，產品標籤、說明書或包裝相關規定」，並自即日生效

Table of Contents

Issuance Date | Subject

Medical Devices Act Article 13

April 28, 2021 Established "Exemption for Individual Permit for Operation of Medical Device Self-Service Vending Machines Set Up Separately by Medical Device Businesses (Pharmacies) for Retail Sales Permits," effective from May 1, 2021.

Medical Devices Act Article 14

March 30, 2021 Established "Scope and Types of Medical Device Retail Business That Pharmacies May Concurrently Operate," effective from May 1, 2021.

Medical Devices Act Article 18

April 29, 2021 Established "Types of Medical Devices Sold Through Remote Communication Channels and Compliance Requirements," effective from May 1, 2021.

June 25, 2021 Established "Types of Medical Devices Permitted to Be Sold via Vending Machines and Requirements for Such Sales," effective immediately.

Medical Devices Act Article 19

April 28, 2021 Established "Medical Devices Required to Establish and Retain Source and Flow Data" and "Items of Medical Devices Required to Report Source and Flow Data," effective immediately.

Medical Devices Act Article 22

July 16, 2021 Established "Items Exempt from Obtaining Medical Device Manufacturing Permits," effective immediately.

Medical Devices Act Article 24

March 18, 2021 Established "Items of Medical Devices and Vendors Required to Establish a Good Distribution Practice (GDP) System under Article 24 of the Medical Devices Act," effective from May 1, 2023.

Medical Devices Act Article 25

April 13, 2021 Established "Items of Medical Devices That Must Obtain Market Approval through Registration," effective from October 1, 2021.

Medical Devices Act Article 30

August 15, 2023 Established "Specifications, Test Methods and Performance Requirements for Certain Medical Device Items," effective until September 1, 2024.

Medical Devices Act Article 33

April 28, 2021 Established "Regulations on Labels, Instructions or Packaging of Medical Devices Exempt from Including Manufacture Date, Expiration Date, or Shelf Life," effective from May 1, 2021.

June 1, 2021 Amended "Warnings and Precautions Required on Labels, Instructions, or Packaging of Certain Medical Devices," effective immediately.

August 5, 2021 Established "Regulations on Product Labels, Instructions or Packaging in Cases Where the Central Competent Authority Directly Registers and Cancels Original Permits pursuant to Paragraph 4, Article 25 of the Medical Devices Act," effective immediately.

Translated by RegDesk AI

發文日期	主旨
112 年 2 月 13 日	訂定「醫療器材標籤應刊載單一識別碼規定」，並自即日生效
112 年 3 月 29 日	訂定「得以電子化說明書取代中文說明書之醫療器材品項及其標籤或包裝應加註事項」，並自即日生效
醫療器材管理法第 37 條	
110 年 4 月 27 日	訂定「無顯著風險之醫療器材臨床試驗態樣」，並自中華民國一百十年五月一日生效
醫療器材管理法第 44 條	
110 年 4 月 22 日	公告訂定「除日戴型每日拋棄式隱形眼鏡外，其餘隱形眼鏡之廣告，以登載於專供醫事人員閱聽之醫療刊物、傳播工具，或專供醫事人員參與之醫療學術性相關活動為限」，並自中華民國一百十年五月一日生效
醫療器材管理法第 47 條	
110 年 4 月 28 日	訂定「應執行安全監視之醫療器材品項」，並自中華民國一百十年五月一日生效
醫療器材管理法第 81 條	
110 年 4 月 15 日	訂定「使用醫療器材蒐集、處理或利用個人資訊者，其替代書面同意之方式」，並自中華民國一百十年五月一日生效

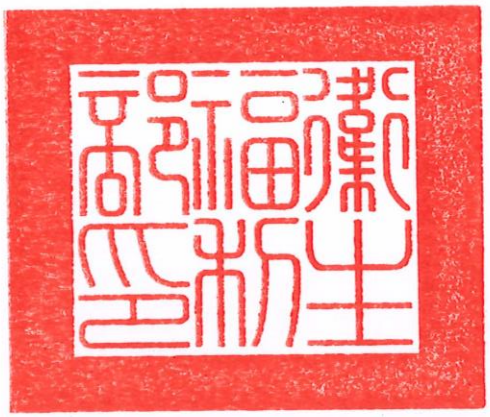
164	
Issuance Date	Subject
February 13, 2023	Stipulation of the "Regulations Governing the Labeling of Unique Device Identifiers on Medical Device Labels," effective as of the date of issuance.
March 29, 2023	Stipulation of the "Medical Device Items Permitted to Use Electronic Instructions for Use in Lieu of Chinese Instructions for Use and Items to Be Indicated on Their Labels or Packaging," effective as of the date of issuance.
Article 37 of the Medical Devices Act	
April 27, 2021	Stipulation of "Types of Clinical Trials of Medical Devices with No Significant Risk," effective as of May 1, 2021.
Article 44 of the Medical Devices Act	
April 22, 2021	Announcement and stipulation that, "Except for daily disposable contact lenses (daily-wear type), advertisements for other contact lenses are limited to publication in medical journals or media exclusively for the use of medical professionals, or in medical academic events exclusively for participation by medical professionals," effective as of May 1, 2021.
Article 47 of the Medical Devices Act	
April 28, 2021	Stipulation of the "Medical Device Items Subject to the Execution of Safety Surveillance," effective as of May 1, 2021.
Article 81 of the Medical Devices Act	
April 15, 2021	Stipulation of "Alternative Methods to Written Consent for Those Who Collect, Process, or Use Personal Information via Medical Devices," effective as of May 1, 2021.

Translated by RegDesk AI

【醫療器材商(藥局)分設醫療器材自動販賣機免各別辦理營業處所販賣業許可執照】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年4月28日
發文字號：衛授食字第1101603767號
附件：

裝

主旨：訂定「醫療器材商(藥局)分設醫療器材自動販賣機免各別辦理營業處所販賣業許可執照」，並自中華民國一百十年五月一日生效。

訂

依據：醫療器材管理法第十三條第三項。

公告事項：訂定「醫療器材商(藥局)分設醫療器材自動販賣機免各別辦理營業處所販賣業許可執照」。

線

部長陳時中

第一頁（共一頁）

「Medical Device Dealer (Pharmacy Bureau) Subdivision Medical Device Vending Machine Variants Handling Operating Location Business Permit Approval」

Ministry of Health and Welfare Announcement

Document Date: April 28, 110th year of the Republic of China

Reference: Medical Device No. 1101603767

Attachments:

Main Content: The stipulation for "Medical Device Dealer (Pharmacy Bureau) Subdivision Medical Device Vending Machine Variants Handling Operating Location Business Permit Approval," effective from May 1st of the Republic of China Year 110.

According to: Medical Device Management Act Article 13, Clause 3.

Announcement Item: The stipulation for "Medical Device Dealer (Pharmacy Bureau) Subdivision Medical Device Vending Machine Variants Handling Operating Location Business Permit Approval."

Minister

Page 1 (of 1)

165

Translated by RegDesk AI

【藥局得兼營醫療器材零售業務之範圍及種類】

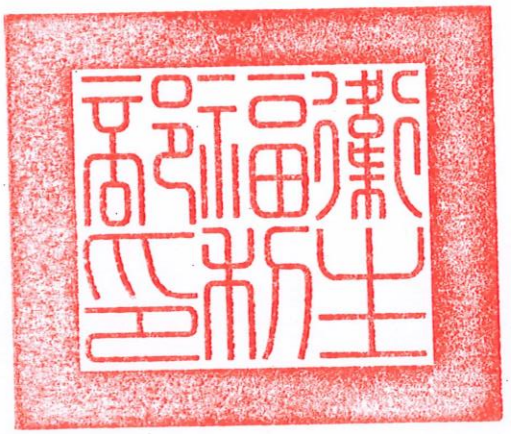
檔　　號：
保存年限：

裝

訂

線

衛生福利部　公告



發文日期：中華民國110年3月30日
發文字號：衛授食字第1101602032號
附件：

主旨：訂定「藥局得兼營醫療器材零售業務之範圍及種類」，並自中華民國一百十年五月一日生效。

依據：醫療器材管理法第十四條第二項。

公告事項：藥局得兼營一定等級之醫療器材零售業務之範圍及種類如下：

一、醫療器材分類分級管理辦法所定第一等級之醫療器材。

二、醫療器材分類分級管理辦法所定非植入式第二等級及第三等級之醫療器材。

部長陳時中

第一頁（共一頁）

□Scope and Types of Retail Business of Pharmacies Engaged in Medical Devices□

Ministry of Health and Welfare Announcement

Issued date: March 30th, 2021

Document Number: Shu-Jiao-Zi No. 1101602032

Attachment:

Subject: Stipulating the "Scope and Types of Retail Business of Pharmacies Engaged in Medical Devices," effective from May 1st, 2021.

Basis: According to Article 14, Paragraph 2, Item 1 of the Medical Devices Management Act.

Announcement: The scope and types of retail business of pharmacies engaged in Class II medical devices are stipulated as follows:

1. Class I medical devices specified by the Medical Device Classification Management Office.

2. Class II and non-implantable Class III medical devices specified by the Medical Device Classification Management Office.

Minister: Chen Shi-Chung

Page 1 (Total 1 Page)

166

Translated by RegDesk AI

【通訊交易通路販售醫療器材之品項及應遵行事項】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年4月29日
發文字號：衛授食字第1101601942號
附件：「通訊交易通路販售醫療器材之品項及應遵行事項」

裝

主旨：訂定「通訊交易通路販售醫療器材之品項及應遵行事項」，並自中華民國一百十年五月一日生效。

訂

依據：醫療器材管理法第十八條。

公告事項：訂定「通訊交易通路販售醫療器材之品項及應遵行事項」。

線

部長陳時中

第一頁（共一頁）

[Matters to be Complied with for Communication Transactions and Online Sales of Medical Devices]

Document No.:

Retention Period:

Issuance Date: April 29, 2021 (Republic of China Year 110)

Regulation Reference Number: Wei-Jian-Zhi No. 1101601942

Attachment: "Matters to be Complied with for Communication Transactions and Online Sales of Medical Devices"

Subject: Formulate the "Matters to be Complied with for Communication Transactions and Online Sales of Medical Devices," effective from May 1, 2021 (Republic of China Year 110).

According to: Article 18 of the Medical Device Management Act.

Announcement: Formulate the "Matters to be Complied with for Communication Transactions and Online Sales of Medical Devices."

Minister

First Page (Total One Page)

Translated by RegDesk AI

通訊交易通路販售醫療器材之品項及應遵行事項

一、本規定依醫療器材管理法(以下簡稱本法)第十八條規定訂定之。

二、本規定用詞，定義如下：

(一)通訊交易通路：指透過廣播、電視、電話、傳真、型錄、報紙、雜誌、網際網路、傳單或其他類似之方法，使消費者未能實際檢視醫療器材而為買賣之通路。

(二)通訊交易通路業者：指提供通訊交易通路予醫療器材商(藥局)從事醫療器材販售業務之業者。

三、於通訊交易通路販售醫療器材者，應符合下列資格之一：

(一)依本法第十三條規定核准登記之醫療器材商。

(二)依藥事法第三十四條規定核准登記之藥局。

四、於前點通路販售之醫療器材，以第一等級及附件所列之第二等級醫療器材品項為限。

五、醫療器材商(藥局)於通訊交易通路販售醫療器材，應同時於其通路提供消費者下列資訊：

(一)醫療器材品名、許可證字號或登錄字號、許可證所有人或登錄者之名稱及地址、製造業者名稱及地址。

(二)醫療器材商(藥局)之名稱、地址、許可執照字號及諮詢專線電話。

(三)加註「消費者使用前應詳閱醫療器材說明書」。

(四)具量測功能之產品，其定期校正服務之項目及據點資訊。

六、於通訊交易通路提供之資訊，其內容涉及醫療器材廣告者，應依本法第四十一條第一項規定辦理，始得為之。

七、違反第三點規定，於通訊交易通路販售醫療器材，係違反本法第十三條第一項規定，依本法第七十條第一項第一款規定處新臺幣三萬元以上一百萬元以下罰鍰。

八、有下列情形之一者，依本法第七十條第一項第三款規定，處新臺幣三萬元以上一百萬元以下罰鍰：

(一)違反第四點規定，販售非屬第一等級或附件所列之第二等級醫療器材品項。

(二)違反第五點規定，未提供資訊或提供資訊不完足。

Provisions and Compliance for Trading in Medical Devices through Telecommunications

1. These regulations are established under Article 18 of the Medical Device Management Act (hereinafter referred to as "the Act").

2. Definitions used in these regulations are as follows:

(1) Telecommunication Channel: Refers to using telecommunication tools like broadcast, television, phone, fax, flyers, newspapers, magazines, internet, radio, or other similar methods to enable buyers to purchase medical devices through communication.

(2) Telecommunication Trader: Refers to individuals or businesses engaged in selling medical devices (including pharmacies) through telecommunication channels.

3. Individuals or entities trading in medical devices through telecommunications must meet one of the following criteria:

(1) Be a registered medical device trader according to Article 13 of the Act.

(2) Be a registered pharmacy according to Article 30 of the Pharmaceutical Affairs Act.

4. When selling medical devices through telecommunication, products in the First Class and its accessories or Second Class medical devices must be included.

5. When providing telecommunication services for purchasing medical devices, the following must be disclosed at the same time:

(1) The name of the medical device, its registration code or serial number, the name of the certificate holder or manufacturer, and the address and manufacturing address of the facility.

(2) The name and address of the medical device trader (pharmacy). Telephone numbers or fax numbers for inquiries must be provided.

(3) Additional warnings such as "please read the detailed medical device instructions carefully before use."

(4) Information on the functionality and limitations of the products, their potential after-sales service, and return policy specifics.

6. Entities involved in telecommunication trading of medical devices must determine if any advertisements include related medical device content. Compliance with Article 41 of the Act is required before proceeding.

7. Violations of the third provision in telecommunication trading of medical devices, breaching Article 63, will result in fines ranging from 30,000 to 1,000,000 NT dollars according to Article 75 of the Act.

8. Under the following circumstances, fines between 30,000 to 100,000 NT dollars will be imposed based on Article 76:

(1) Violating Article 20, selling non-certified First Class medical devices or Second Class medical device products.

(2) Violating Article 50, insufficient or incomplete provision of information.

Page 168

Translated by RegDesk AI

附件 醫療器材商及藥局得於通訊交易通路販售之第二等級醫療器材品項

項次	品項代碼*	名稱	產品示例
1	E.2770	阻抗式體積描記器(阻抗式週邊血流描記器)	體脂計
2	L.5300	衛生套(保險套)	保險套
3	L.5310	含殺精劑的衛生套	保險套
4	L.5460	具香味或除臭的衛生棉塞	衛生棉條
5	L.5470	無香味的衛生棉塞	衛生棉條
6	I.4040	醫療用衣物	手術用口罩、手術用 N95口罩
7	I.0004	酒精棉片	酒精棉片、酒精棉球
8	I.0005	優碘棉片	優碘棉片、碘液棉棒、碘液紗布
9	I.4014	外部使用非吸收式紗布或海綿球	凡士林紗布
10	J.5240	醫療用黏性膠帶及黏性繃帶	免縫膠帶
11	M.5918	硬式透氣隱形眼鏡保存用產品	硬式隱形眼鏡清潔液、保養液、保存液、護理液、濕潤液、雙氧系統、去蛋白錠、隱形眼鏡用緩衝生理食鹽水
12	M.5928	軟式隱形眼鏡保存用產品	軟式隱形眼鏡清潔液、保養液、保存液、護理液、濕潤液、雙氧系統、去蛋白錠、隱形眼鏡用緩衝生理食鹽水
13		醫療器材軟體	第二等級醫療器材軟體
14	E.1120	血壓壓脈帶	血壓壓脈帶、血壓袖帶、血壓量測臂帶
15	L.5400	月經量杯	月經杯、月事杯、月亮杯
16	O.3800	醫療用電動代步器	醫療用電動代步車
17	O.3860	動力式輪椅	電動輪椅、安裝於輪椅之電動輔助推行器
18	G.5220	耳鼻喉佈施藥裝置及其搭配使用之物質	海水洗鼻器、海水鼻用噴霧器、洗鼻鹽
19	J.2910	臨床電子體溫計	耳溫槍、耳溫槍專用耳套、額溫槍

*醫療器材品項名稱及鑑別依醫療器材分類分級管理辦法之附表規定。

Appendix: Second-Class Medical Device Items Store Notice for Medical Material and Trading Bureau

Item No.	Produ... Code	Name	Product Example
1	E. 2770	Sphygmomanometer (electronic/mercury)	Sphygmomanometer
2	L. 5300	Hygiene Kit (Protective)	Protective Kit
3	L. 5310	General Hygiene Kit	Hygiene Kit
4	L. 5460	Sterile Surgical Gown	Sterile Surgical Gown
5	L. 5470	Non-Sterile Surgical Gown	Non-Sterile Surgical Gown
6	T. 4040	Protective Mask	Protective Mask, N95 Mask
7	M. 0041	Alcohol Pad	Alcohol Pad, Alcohol Ball
8	M. 0005	Disinfectant Sheet	Disinfectant Sheet, Disinfectant Wipes, Disinfectant Cloth
9	T. 4014	External Device for Eye Wash or Shower	Eye Wash Station
10	J. 5240	Free Sales of Medical Gloves	Free Sale Gloves
11	M. 5918	Hard Contact Lens Care Products	Hard Contact Lens Solution, Care Solution, Protein Remover Tablet, Disinfectant Kit for Lenses
12	M. 5928	Soft Contact Lens Care Products	Soft Contact Lens Solution, Care Solution, Protein Remover Tablet, Disinfectant Kit for Lenses
13	-	Medical Equipment Software	Second-Class Medical Device Software
14	E. 1120	Blood Pressure Monitor	Blood Pressure Monitor, Blood Pressure Cuff, Blood Pressure Measuring Device
15	L. 5400	Menstrual Cup	Menstrual Cup
16	O. 3800	Medical Walking Aid	Medical Walking Aid, Walking Stick
17	O. 3860	Mobility Aid	Mobility Aid, Wheelchair, Mobility Scooter
18	G. 5220	Nasal Irrigation Device and Accessories	Nasal Irrigation, Nasal Irrigation Solution, Washing Solution
19	J. 2910	Electronic Medical Thermometer	Thermometer, Infrared Forehead Thermometer, Ear Thermometer

The medical device items listed refer to medical device categories specified in the Medical Device Management Distribution Regulations.

Translated by RegDesk AI

【得以自動販賣機販售之醫療器材種類及其販售之應遵循事項】

檔　　號：
保存年限：

裝

衛生福利部　公告



發文日期：中華民國110年6月25日
發文字號：衛授食字第1101606015號
附件：「得以自動販賣機販售之醫療器材種類及其販售之應遵循事項」1份

訂

主旨：訂定「得以自動販賣機販售之醫療器材種類及其販售之應遵循事項」，並自即日生效。

依據：醫療器材管理法第十八條。

公告事項：訂定「得以自動販賣機販售之醫療器材種類及其販售之應遵循事項」。

線

部長陳時中

第一頁（共一頁）

「Matters to Follow Regarding Types of Medical Devices That Can Be Sold Using Vending Machines and Their Sales」

Issue Number:

Reference Number:

Ministry of Health and Welfare Announcement

Issue Date: June 25, 2021 (Republic of China Year 110)

Document Number: Shu-Shou-Zi No. 1101606015

Attachment: "Matters to Follow Regarding Types of Medical Devices That Can Be Sold Using Vending Machines and Their Sales"

Subject: Announcement of "Matters to Follow Regarding Types of Medical Devices That Can Be Sold Using Vending Machines and Their Sales," effective immediately.

According to: Article 18 of the Pharmaceutical Affairs Act.

Matters of Announcement: Matters to Follow Regarding Types of Medical Devices That Can Be Sold Using Vending Machines and Their Sales.

Minister:

Page 1 (out of 1)

170

Translated by RegDesk AI

得以自動販賣機販售之醫療器材種類及其販售之應遵循事項

一、本事項依醫療器材管理法(以下簡稱本法)第十八條規定訂定之。

二、醫療器材商(藥局)得以自動販賣機販售附表所列之醫療器材種類。

三、醫療器材商(藥局)申請於非登記之處所，以自動販賣機販賣醫療器材，應依本法第十三條第二項及第三項規定，檢附下列文件資料，向所在地直轄市、縣(市)主管機關提出:

(一)自動販賣機設置地點、設置期間及販賣醫療器材種類之列冊。

(二)自動販賣機設置地點所屬業主之同意書及同意設置期限。

(三)自動販賣機具溫溼度控制功能之佐證資料。但設置地點位於室內者，免附。

四、醫療器材商(藥局)依前點申請以自動販賣機販賣醫療器材，其登記事項如下；變更時，應辦理變更登記：

(一)自動販賣機設置地點。

(二)販賣之醫療器材種類。

五、醫療器材商(藥局)經核准以自動販賣機販賣醫療器材者，應依其登記事項為之，並遵循下列事項:

(一)自動販賣機外觀應標示核准登記醫療器材商(藥局)之許可執照字號、名稱、地址及服務專線。如消費者無法於購買前得知販賣之醫療器材產品資訊者，應於機身標示該醫療器材之許可證字號、中文品名、英文品名、許可證持有醫療器材商名稱、製造廠名稱、地址及其他相關資訊。

(二)醫療器材商(藥局)停業、歇業，或設置地點所屬業主同意設置期限屆至時，已設置之自動販賣機，應移除外觀標示及其全部醫療器材，並檢附佐證資料，向原核准之醫療器材商(藥局)所在地直轄市、縣(市)主管機關辦理註銷登記。

Sale of Medical Devices by Vending Machines and Related Compliance Matters

I. This matter is regulated according to the Medical Device Management Act (hereinafter referred to as the “Act”) Article XVIII II.

II. Health Departments (Bureaus) shall approve the types of medical devices to be sold through vending machines.

III. Health Departments (Bureaus) shall apply for non-restricted records to sell medical devices through vending machines, following Article 13, Item 2 and Item 3 of the Act. Submit the following documents to the responsible local city or county authority for review:

(1) Main Items to be Described:

(1) Vending machine installation location and surrounding environment layout for the sale of medical devices.

(2) Ownership and consent documents for the vending machine installation location.

(3) Vending machine storage temperature control mechanism description. If vending machine installation location satisfies storage space requirements, this may be exempted.

IV. When applying for the sale of medical devices through vending machines, Health Departments (Bureaus) shall register the items as follows:

(1) Vending machine installation location.

(2) Type of medical devices sold.

V. After approval by Health Departments (Bureaus) for the sale of medical devices through vending machines, the following compliance matters must be observed:

(1) External display of the vending machine should indicate the Health Department (Bureau) registration number, business license number, name, address, and service records. If buyers cannot obtain information of the purchased medical device, labeling should show the device’s registration number, Chinese name, English name, permit holder's medical device business name, manufacturer name, and address or other relevant details.

(2) If a Health Department (Bureau) business shuts down, relocates, or changes the installation location to a place not originally registered, the original vending machine should be relocated, and the complete medical device notation must be displayed. Documentation should be submitted to the original Health Department (Bureau) for any changes, for registration by the responsible local city or county authority.

Translated by RegDesk AI

附表

得以自動販賣機販售之醫療器材種類表：

項次	醫療器材種類	所屬品項代碼及名稱	鑑別範圍或產品敘述
1	衛生套(保險套)	L.5300衛生套(保險套) L.5310含殺精劑的衛生套	醫療器材分類分級管理辦法相關規定。
2	醫用口罩	I.4040醫療用衣物	
3	冷熱敷包	O.5710醫療用可丟棄式的冷熱敷包	
4	衛生棉塞	L.5460具香味或除臭的衛生棉塞 L.5470無香味的衛生棉塞	
5	月經量杯	L.5400月經量杯	

Appendix

List of Medical Devices Allowed for Sale in Vending Machines:

Item No.	Medical Device Category	Product Code and Name	Remarks or Unit Quantity
1	Sanitary Pads (Including Tampons)	L. 5300 Sanitary Pads (Including Tampons)	
L. 5310 Sanitary Pads with Medicinal Ingredients	Medical device classification management regulations apply.		
2	Medical Masks	I. 4010 Medical Masks	
3	Cold/Hot Packs	O. 5710 Medical Reusable Cold/Hot Packs	
4	Sanitary Cotton Balls	L. 5460 Scented or Medicinal Sanitary Cotton Balls	
L. 5470 Unscented Sanitary Cotton Balls			
5	Menstrual Cups	L. 5400 Menstrual Cups	

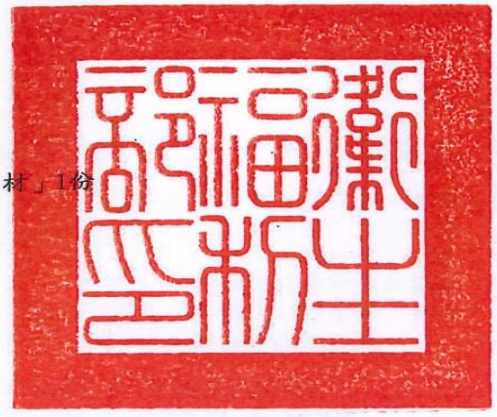
Page 172

Translated by RegDesk AI

【應建立與保存來源及流向資料之醫療器材及應申報來源及流向資料之醫療器材品項】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年4月28日
發文字號：衛授食字第1101603553號
附件：「應建立與保存來源及流向資料之醫療器材」1份

裝

主旨：訂定「應建立與保存來源及流向資料之醫療器材」及「應申報來源及流向資料之醫療器材品項」，並自中華民國一百十年五月一日生效。

訂

依據：醫療器材管理法第十九條第一項及第二項。

公告事項：

一、「應建立與保存來源及流向資料之醫療器材」為醫療器材分類分級管理辦法所定第二等級及第三等級植入式醫療器材如附件。

二、「應申報來源及流向資料之醫療器材品項」依醫療器材分類分級管理辦法所定如下：

(一)E.3610植入式心律器之脈搏產生器。

(二) I.3540矽膠充填之乳房彌補物。

(三)L.5980經陰道骨盆腔器官脫垂治療用手術網片。

線

部長陳時中

第一頁（共一頁）

[Establishment and Preservation of Source and Flow Information for Medical Devices Required for Declaration]

Ministry of Health and Welfare Announcement

Document Date: April 28, 2021

Document Number: Health Insurance No. 1101505335

Subject: "Establishment and Preservation of Source and Flow Information for Medical Devices Required for Declaration"

Main Content:

Prescribe the regulation of "Establishment and Preservation of Source and Flow Information for Medical Devices" and "Medical Devices Required for Declaration of Source and Flow Information," effective from May 1st, Republic of China Year 110.

According to: Article 19, Paragraph 1 and 2 of the Medical Device Management Act.

Announcements:

1. The regulation of "Establishment and Preservation of Source and Flow Information for Medical Devices" as a second or third-level medical device designated by the division management of the competent authority.

2. The devices required for declaration of source and flow information are specified as follows, according to their management level:

- (1) E.3610 Implanted Cardiac Pacemakers.

- (2) I.3540 Hip Joint Replacement or Knee Joint Auxiliary.

- (3) L.5980 Implantable Fine Mesh for Hernia Repair in Surgery.

Minister: Chen Shizhong

Page 1 (Total 1 page)

Translated by RegDesk AI

「應建立與保存來源及流向資料之醫療器材」附件

項	品項代碼	中文名稱	英文名稱	等級
1	E.0001	心血管支架	Cardiovascular stent	2,3
2	E.0006	血管內移植系統	Endovascular graft system	3
3	E.3250	血管夾	Vascular clip	2
4	E.3260	靜脈腔室夾	Vena cava clip	2
5	E.3300	動脈栓塞裝置	Arterial embolization device	3
6	E.3375	心血管之血管內過濾器	Cardiovascular intravascular filter	2
7	E.3450	血管移植彌補物	Vascular graft prosthesis	2
8	E.3460	血管內縫線系統	Endovascular Suturing System	2
9	E.3470	聚丙烯、聚乙烯、對苯二甲酸等材質製成之心內補片或小拭子	Intracardiac patch or pledget made of polypropylene,polyethylene terephthalate, or polytetrafluoroethylene	2
10	E.3545	心室血管繞道術(輔助)裝置	Ventricular bypass (assist) device	3
11	E.3610	植入式心律器之脈搏產生器	Implantable pacemaker pulse generator	3
12	E.3620	心律器導線接頭	Pacemaker lead adaptor	2
13	E.3680	心血管用永久或暫時性之心律調節器電極	Cardiovascular permanent or temporary pacemaker electrode	2,3
14	E.3710	心律調節器修復或置換之材料	Pacemaker repair or replacement material	3
15	E.3800	環狀成形術環	Annuloplasty ring	2
16	E.3850	頸動脈竇神經刺激器	Carotid sinus nerve stimulator	3
17	E.3925	心臟瓣膜置換物	Replacement heart valve	3
18	E.4450	血管夾	Vascular clamp	2
19	E.4510	心尖閉合器	Apical closure device	2
20	F.3060	牙科使用金基合金和貴重金屬合金	Gold based alloys and precious metal alloys for clinical use	2
21	F.3070	牙科用汞齊、水銀、汞齊合金	Dental amalgam, mercury, and amalgam alloy	2
22	F.3250	氫氧化鈣窩洞襯底	Calcium hydroxide cavity liner	2
23	F.3260	窩洞塗料	Cavity varnish	2
24	F.3310	樹脂充填用塗覆材料	Coating material for resin fillings	2
25	F.3640	骨內植體	Endosseous implant	3
26	F.3645	骨膜下植體材	Subperiosteal implant material	2

"Reference for Establishing and Retaining Sources and Relevant Materials for Medical Devices" Appendix

N..	Pr... Co...	Chinese Name	English Name	L...
1	E....	Cardiovascular stent	Cardiovascular stent	2, 3
2	E....	Endovascular graft system	Endovascular graft system	3
3	E....	Vascular clip	Vascular clip	2
4	E....	Vena cava clip	Vena cava clip	2
5	E....	Arterial embolization device	Arterial embolization device	3
6	E....	Cardiovascular intravascular filter	Cardiovascular intravascular filter	2
7	E....	Vascular graft prosthesis	Vascular graft prosthesis	2
8	E....	Endovascular Suturing System	Endovascular Suturing System	2
9	E....	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene	Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene	2
10	E....	Ventricular bypass (assist) device	Ventricular bypass (assist) device	3
11	E....	Implantable pacemaker pulse generator	Implantable pacemaker pulse generator	3
12	E....	Pacemaker lead adaptor	Pacemaker lead adaptor	2
13	E....	Cardiovascular permanent or temporary pacemaker electrode	Cardiovascular permanent or temporary pacemaker electrode	2, 3
14	E....	Pacemaker repair or replacement material	Pacemaker repair or replacement material	3
15	E....	Annuloplasty ring	Annuloplasty ring	2
16	E....	Carotid sinus nerve stimulator	Carotid sinus nerve stimulator	3
17	E....	Replacement heart valve	Replacement heart valve	3
18	E....	Vascular clamp	Vascular clamp	2
19	E....	Apical closure device	Apical closure device	2
20	F....	Gold based alloys and precious metal alloys for clinical use	Gold based alloys and precious metal alloys for clinical use	2
21	F....	Dental amalgam, mercury, and amalgam alloy	Dental amalgam, mercury, and amalgam alloy	2
22	F....	Calcium hydroxide cavity liner	Calcium hydroxide cavity liner	2
23	F....	Cavity varnish	Cavity varnish	2
24	F....	Coating material for resin fillings	Coating material for resin fillings	2
25	F....	Endosseous implant	Endosseous implant	3
26	F....	Subperiosteal implant material	Subperiosteal implant material	2

Translated by RegDesk AI

27	F.3680	聚四氟乙烯玻璃狀碳材料(聚化玻璃黏著劑)	Polytetrafluoroethylene (PTFE) vitreous carbon material	2
28	F.3690	樹脂牙材	Tooth shade resin material	2
29	F.3710	卑金屬合金	Base metal alloy	2
30	F.3765	凹窩封閉劑及調節劑	Pit and fissure sealant and conditioner	2
31	F.3820	根管充填樹脂	Root canal filling resin	2,3
32	F.3890	根管固定夾板	Endodontic stabilizing splint	2
33	F.3930	牙槽修復材料	Bone grafting material	2,3
34	F.3940	全顳顎關節彌補物	Total temporomandibular joint prosthesis	3
35	F.3950	顳骨關節盂彌補物	Glenoid fossa prosthesis	3
36	F.3960	下頜髁彌補物	Mandibular condyle prosthesis	3
37	F.3970	關節間盤彌補物(內置式植入物)	Interarticular disc prosthesis (interpositional implant)	3
38	F.4760	骨板	Bone plate	2
39	F.4880	骨內固定螺釘或金屬線	Intraosseous fixation screw or wire	2
40	F.5560	電子式唾液刺激系統	Electrical salivary stimulatory system	2
41	F.6660	牙科用瓷粉	Porcelain powder for clinical use	2
42	G.0001	人工耳蝸植入器	Cochlear implant	3
43	G.3315	鼓膜接觸式助聽器	Tympanic membrane contact hearing aid	2
44	G.3430	中耳模	Middle ear mold	2
45	G.3450	部分聽小骨置換物	Partial ossicular replacement prosthesis	2
46	G.3495	全聽小骨置換物	Total ossicular replacement prosthesis	2
47	G.3620	耳鼻喉科用合成聚合物材料	Ear, nose, and throat synthetic polymer material	2
48	G.3695	下頜骨植入式臉部彌補物	Mandibular implant facial prosthesis	2
49	G.3730	喉部彌補物(Taub 式)	Laryngeal prosthesis (Taub design)	2
50	G.3760	球囊切開術釘(Cody 氏釘)	Sacculotomy tack (Cody tack)	2
51	G.3820	內淋巴液分流器	Endolymphatic shunt	2
52	G.3850	含瓣膜式內淋巴液分流導管	Endolymphatic shunt tube with valve	2
53	G.3880	鼓室通氣管	Tympanostomy tube	2

27	F.3680	Polytetrafluoroethylene (PTFE) vitreous carbon material	2
28	F.3690	Tooth shade resin material	2
29	F.3710	Base metal alloy	2
30	F.3765	Pit and fissure sealant and conditioner	2
31	F.3820	Root canal filling resin	2, 3
32	F.3890	Endodontic stabilizing splint	2
33	F.3930	Bone grafting material	2, 3
34	F.3940	Total temporomandibular joint prosthesis	2
35	F.3950	Glenoid fossa prosthesis	3
36	F.3960	Mandibular condyle prosthesis	3
37	F.3970	Interarticular disc prosthesis (interpositional implant)	2
38	F.4760	Bone plate	2
39	F.4880	Intraosseous fixation screw or wire	2
40	F.5560	Electrical salivary stimulatory system	2
41	F.6660	Porcelain powder for clinical use	2
42	G.0001	Cochlear implant	3
43	G.3315	Tympanic membrane contact hearing aid	2
44	G.3430	Middle ear mold	2
45	G.3450	Partial ossicular replacement prosthesis	2
46	G.3495	Total ossicular replacement prosthesis	2
47	G.3620	Ear, nose, and throat synthetic polymer material	2
48	G.3695	Mandibular implant facial prosthesis	2
49	G.3730	Laryngeal prosthesis (Taub design)	2
50	G.3760	Sacculotomy tack (Cody tack)	2
51	G.3820	Endolymphatic shunt	2
52	G.3850	Endolymphatic shunt tube with valve	2
53	G.3880	Tympanostomy tube	2

Translated by RegDesk AI

54	G.3930	含半通透膜鼓室通氣管	Tympanostomy tube with semipermeable membrane	2
55	H.3350	膨脹式陰莖植入物	Penile inflatable implant	3
56	H.3630	硬式陰莖植入物	Penile rigidity implant	2
57	H.3750	睪丸彌補物	Testicular prosthesis	3
58	H.4620	輸尿管支架	Ureteral stent	2
59	H.5015	胰液引流支架與施放系統	Pancreatic drainage stent	2
60	H.5140	膀胱殘餘尿淨空用尿道置入式幫浦	Urethral insert with pump for bladder drainage	2
61	H.5270	植入式電子排尿自制裝置	Implanted electrical urinary continence device	3
62	H.5280	植入式機械/水壓式排尿自制裝置	Implanted mechanical/hydraulic urinary continence device	3
63	H.5530	植入式前列腺組織夾取系統	Implantable transprostatic tissue retractor system	2
64	H.5540	血液通路裝置及其附件	Blood access device and accessories	2
65	H.5930	女性下泌尿道症用直腸控制系統	Rectal control system	2
66	I.0002	膠原蛋白植入劑	Collagen implant	3
67	I.0007	玻尿酸植入物	Hyaluronic Acid Implants	3
68	I.0010	抗沾黏屏障材料	Adhesion Barrier Material	3
69	I.3300	外科用網片	Surgical mesh	2
70	I.3500	含碳纖維合成物之聚四氟乙烯之植入物材料	Polytetrafluoroethylene with carbon fibers composite implant material	2
71	I.3530	可充填生理食鹽水之矽膠乳房彌補物	Silicone inflatable breast prosthesis	3
72	I.3540	矽膠充填之乳房彌補物	Silicone gel-filled breast prosthesis	3
73	I.3550	下巴彌補物	Chin prosthesis	2
74	I.3590	耳朵彌補物	Ear prosthesis	2
75	I.3610	食道彌補物	Esophageal prosthesis	2
76	I.3680	鼻彌補物	Nose prosthesis	2
77	I.3720	氣管彌補物	Tracheal prosthesis	2
78	I.4010	組織黏著劑	Tissue adhesive	2,3
79	I.4015	含聚二甲基二烯丙基氯化銨(pDADMAC)成分之創傷覆蓋材	Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive	2
80	I.4300	可植入式夾子	Implantable clip	2

54	G.39..	Tympanostomy tube with semipermeable membrane	2
55	H.33...	Penile inflatable implant	3
56	H.36...	Penile rigidity implant	2
57	H.37...	Testicular prosthesis	3
58	H.46...	Ureteral stent	2
59	H.50...	Pancreatic drainage stent	2
60	H.51...	Urethral insert with pump for bladder drainage	2
61	H.52...	Implanted electrical urinary continence device	3
62	H.52...	Implanted mechanical/hydraulic urinary continence device	3
63	H.55...	Implantable transprostic tissue retractor system	2
64	H.55...	Blood access device and accessories	2
65	H.59...	Rectal control system	2
66	1.00...	Collagen implant	3
67	1.00...	Hyaluronic Acid Implants	3
68	1.00...	Adhesion Barrier Material	3
69	1.33...	Surgical mesh	2
70	1.35...	Polytetrafluoroethylene with carbon fibers composite implant material	2
71	1.35...	Silicone inflatable breast prosthesis	3
72	1.35...	Silicone gel-filled breast prosthesis	3
73	1.35...	Chin prosthesis	2
74	1.35...	Ear prosthesis	2
75	1.36...	Esophageal prosthesis	2
76	1.36...	Nose prosthesis	2
77	1.37...	Tracheal prosthesis	2
78	1.40...	Tissue adhesive	2, 3
79	1.40...	Wound dressing with poly (diallyl dimethyl ammonium chloride) (pDADMAC) additive	2
80	1.40...	Implantable clip	2

176

Translated by RegDesk AI

81	I.4490	可吸收性止血劑及敷料	Absorbable hemostatic agent and dressing	3
82	I.4493	可吸收性多醣體交脂類外科用縫合線	Absorbable poly(glycolide/L-lactide) surgical suture	2
83	I.4494	基因重組技術製造之可吸收聚羥基丁酸酯外科縫線	Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology	2
84	I.4495	不銹鋼縫合線	Stainless steel suture	2
85	I.4520	聚四氟乙烯注射物	Polytetrafluoroethylene injectable	3
86	I.4750	植入式縫合釘	Implantable staple	2
87	I.4830	可吸收性腸縫合線	Absorbable surgical gut suture	2
88	I.4840	可吸收性聚對二氧環已酮外科縫合線	Absorbable polydioxanone surgical suture	2
89	I.5000	不可吸收性聚對苯二甲酸乙二酯縫合線	Nonabsorbable poly(ethylene terephthalate)surgical suture	2
90	I.5010	不可吸收性聚丙烯縫合線	Nonabsorbable polypropylene surgical suture	2
91	I.5020	不可吸收性聚醯胺縫合線	Nonabsorbable polyamide surgical suture	2
92	I.5030	不可吸收性絲縫合線	Natural nonabsorbable silk surgical suture	2
93	I.5035	非吸收式膨體聚四氟乙烯手術縫合線	Nonabsorbable expanded polytetrafluoroethylene surgical suture	2
94	K.1330	深度電極	Depth electrode	2
95	K.5030	動脈瘤縫合術用甲基丙烯酸甲酯	Methyl methacrylate for aneurysmorrhaphy	2
96	K.5150	血管內閉塞導管	Intravascular occluding catheter	3
97	K.5175	頸動脈夾	Cartoid artery clamp	2
98	K.5200	動脈瘤夾	Aneurysm clip	2
99	K.5225	植入式可展延夾	Implanted malleable clip	2
100	K.5275	神經環帶	Nerve cuff	2
101	K.5300	頭顱造型術用甲基丙烯酸甲酯	Methyl methacrylate for cranioplasty	2
102	K.5320	預成形可變式頭顱造型板	Preformed alterable cranioplasty plate	2
103	K.5330	預成形不可變式頭顱造型板	Preformed nonalterable cranioplasty plate	2

81 L4490 Absorbable hemostatic agent and dressing 3

82 I.4493 Absorbable poly(glycolide/L-lactide) surgical suture 2

83 I.4494 Absorbable poly(hydroxybutyrate) surgical suture produced by recombinant DNA technology 2

84 I.4495 Stainless steel suture 2

85 I.4520 Polytetrafluoroethylene injectable 3

86 I.4750 Implantable staple 2

87 I.4830 Absorbable surgical gut suture 2

88 I.4840 Absorbable polydioxanone surgical suture 2

89 I.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture 2

90 I.5010 Nonabsorbable polypropylene surgical suture 2

91 I.5020 Nonabsorbable polyamide surgical suture 2

92 I.5030 Natural nonabsorbable silk surgical suture 2

93 I.5035 Nonabsorbable expanded polytetrafluoroethylene surgical suture 2

94 K.1330 Depth electrode 2

95 K.5030 Methyl methacrylate for aneurysmorrhaphy 2

96 K.5150 Intravascular occluding catheter 2

97 K.5175 Carotid artery clamp 2

98 K.5200 Aneurysm clip 2

99 K.5225 Implanted malleable clip 2

100 K.5275 Nerve cuff 2

101 K.5300 Methyl methacrylate for cranioplasty 2

102 K.5320 Preformed alterable cranioplasty plate 2

103 K.5330 Preformed nonalterable cranioplasty plate 2

177

Translated by RegDesk AI

104	K.5360	頭顱造形板固定器	Cranioplasty plate fastener	2
105	k.5805	重複式經顱磁刺激(rTMS)治療系統	Repetitive transcranial magnetic stimulation system	2
106	K.5820	植入式小腦刺激器	Implanted cerebellar stimulator	3
107	K.5830	植入式膈膜/膈神經刺激器	Implanted diaphragmatic/phrenic nerve stimulator	3
108	K.5840	疼痛舒緩用植入式大腦內/皮質下刺激器	Implanted intracerebral/subcortical stimulator for pain relief	3
109	K.5850	膀胱排空用植入式脊髓刺激器	Implanted spinal cord stimulator for bladder evacuation	3
110	K.5860	植入式神經肌肉刺激器	Implanted neuromuscular stimulator	3
111	K.5870	疼痛舒緩用植入式週邊神經刺激器	Implanted peripheral nerve stimulator for pain relief	2
112	K.5880	疼痛舒緩用植入式脊髓刺激器	Implanted spinal cord stimulator for pain relief	2,3
113	K.5900	預成形頭顱骨接合帶	Preformed craniosynostosis strip	2
114	K.5910	硬膜替代物	Dura substitute	2
115	K.5940	電痙攣治療裝置	Electroconvulsive therapy device	3
116	K.5950	人工栓塞裝置	Artificial embolization device	3
117	L.0004	可吸收性防沾黏材質	Absorable adhesion barrier	3
118	L.3650	輸卵管彌補物	Fallopian tube prosthesis	2
119	L.3900	陰道支架	Vaginal stent	2
120	L.5360	子宮內避孕器及放置器	Contraceptive intrauterine device (IUD) and introducer	3
121	L.5380	輸卵管閉合避孕器及放置器	Contraceptive tubal occlusion device (TOD) and introducer	3
122	L.5980	經陰道骨盆腔器官脫垂治療用手術網片	Surgical mesh for transvaginal pelvic organ prolapse repair	3
123	M.0002	囊袋環	Endocapsular ring	3
124	M.3100	眼科用鉭製夾	Ophthalmic tantalum clip	2
125	M.3300	可吸收之植入物(鞏膜扣環法)	Absorbable implant (scleral buckling method)	2
126	M.3320	眼球植入物	Eye sphere implant	2
127	M.3340	眼外部眼框植入物	Extraocular orbital implant	2
128	M.3400	角膜彌補物	Keratoprosthesis	2
129	M.3600	人工水晶體	Intraocular lens	3
130	M.3920	眼房水閥植入物	Eye valve implant	2

1...	K.5360	Cranioplasty plate fastener	2
1...	K.5805	Repetitive transcranial magnetic stimulation system	2
1...	K.5820	Implanted cerebellar stimulator	3
1...	K.5830	Implanted diaphragmatic/phrenic nerve stimulator	3
1...	K.5840	Implanted intracerebral/subcortical stimulator for pain relief	3
1...	K.5850	Implanted spinal cord stimulator for bladder evacuation	3
1...	K.5860	Implanted neuromuscular stimulator	3
1...	K.5870	Implanted peripheral nerve stimulator for pain relief	2
1...	K.5880	Implanted spinal cord stimulator for pain relief	2...
1...	K.5900	Prefomed craniosynostosis strip	2
1...	K.5910	Dura substitute	2
1...	K.5940	Electroconvulsive therapy device	3
1...	K.5950	Artificial embolization device	3
1...	L.0004	Absorbable adhesion barrier	3
1...	L.3650	Fallopian tube prosthesis	2
1...	L.3900	Vaginal stent	2
1...	L.5360	Contraceptive intrauterine device (IUD) and introducer	3
1...	L.5380	Contraceptive tubal occlusion device (TOD) and introducer	2
1...	L.5980	Surgical mesh for transvaginal pelvic organ prolapse repair	3
1...	M.0002	Endocapsular ring	3
1...	M.3100	Ophthalmic tantalum clip	2
1...	M.3300	Absorbable implant (scleral buckling method)	2
1...	M.3320	Eye sphere implant	2
1...	M.3340	Extraocular orbital implant	2
1...	M.3400	Keratoprosthesis	2
1...	M.3600	Intraocular lens	3
1...	M.3920	Eye valve implant	2

Translated by RegDesk AI
Translated by RegDesk AI
Translated by RegDesk AI

131	M.4155	鞏膜塞	Scleral plug	2
132	M.4270	眼內充填用氣體	Intraocular gas	3
133	M.4275	眼內充填用液體	Intraocular fluid	3
134	N.0003	關節腔玻尿酸植入物	Intraarticular hyaluronic acid implants	3
135	N.3010	骨固定環	Bone fixation cerclage	2
136	N.3015	骨頭異體移植片	Bone heterograft	3
137	N.3020	骨髓內固定桿	Intramedullary fixation rod	2
138	N.3023	體內固化式髓內固定桿	In vivo cured intramedullary fixation rod	2
139	N.3025	被動式肌腱彌補物	Passive tendon prosthesis	2
140	N.3027	PMMA 骨水泥	Polymethylmethacrylate (PMMA) bone cement	2
141	N.3030	單一或多重之金屬類骨固定裝置及附件	Single/multiple component metallic bone fixation appliance and accessories	2
142	N.3040	平滑或螺紋之金屬類骨固定物	Smooth or threaded metallic bone fixation fastener	2
143	N.3045	可吸收鈣鹽骨洞填充裝置	Resorbable calcium salt bone void filler device	2,3
144	N.3050	椎弓板間之脊椎矯正固定物	Spinal interlaminal fixation orthosis	2
145	N.3060	椎體間之脊椎矯正固定物	Spinal intervertebral body fixation orthosis	2
146	N.3070	椎弓螺釘系統	Pedicle screw spinal system	2
147	N.3080	椎體間融合裝置	Intervertebral body fusion device	2,3
148	N.3100	半限制型踝關節之金屬類/複合物類骨水泥式彌補物	Ankle joint metal/composite semi-constrained cemented prosthesis	2
149	N.3110	半限制型踝關節之金屬類/聚合物類骨水泥式彌補物	Ankle joint metal/polymer semi-constrained cemented prosthesis	2
150	N.3120	非限制型踝關節之金屬類/聚合物類骨水泥式彌補物	Ankle joint metal/polymer non-constrained cemented prosthesis	3
151	N.3150	限制型肘關節之金屬類/金屬類或金屬類/聚合物類骨水泥式彌補物	Elbow joint metal/metal or metal/polymer constrained cemented prosthesis	2
152	N.3160	半限制型肘關節之金屬類/聚合物類骨水泥式彌補物	Elbow joint metal / polymer semi-constrained cemented prosthesis	2
153	N.3170	肘關節橈骨(半肘)聚合物類彌補物	Elbow joint radial (hemi-elbow) polymer prosthesis	2

131 M.4155 Scleral plug 2

132 M.4270 Intraocular gas 3

133 M.4275 Intraocular fluid 3

134 N.0003 Intraarticular hyaluronic acid implants 3

135 N.3010 Bone fixation cerclage 2

136 N.3015 Bone heterograft 3

137 N.3020 Intramedullary fixation rod 2

138 N.3023 In vivo cured intramedullary fixation rod 2

139 N.3025 Passive tendon prosthesis 2

140 N.3027 Polymethylmethacrylate (PMMA) bone cement 2

141 N.3030 Single/multiple component metallic bone fixation appliance and accessories 2

142 N.3040 Smooth or threaded metallic bone fixation fastener 2

143 N.3045 Resorbable calcium salt bone void filler device 2,3

144 N.3050 Spinal interlaminal fixation orthosis 2

145 N.3060 Spinal intervertebral body fixation orthosis 2

146 N.3070 Pedicle screw spinal system 2

147 N.3080 Intervertebral body fusion device 2,3

148 N.3100 Ankle joint metal/composite semi-constrained cemented prosthesis 2

149 N.3110 Ankle joint metal/polymer semi-constrained cemented prosthesis 2

150 N.3120 Ankle joint metal/polymer non-constrained cemented prosthesis 3

151 N.3150 Elbow joint metal/metal or metal/polymer constrained cemented prosthesis 2

152 N.3160 Elbow joint metal/polymer semi-constrained cemented prosthesis 2

153 N.3170 Elbow joint radial (hemi-elbow) polymer prosthesis 2

Translated by RegDesk AI

154	N.3180	肘關節肱骨(半肘)金屬類無骨水泥式彌補物	Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis	3
155	N.3200	限制型指關節之金屬類/金屬類無骨水泥式彌補物	Finger joint metal / metal constrained uncemented prosthesis	3
156	N.3210	限制型指關節之金屬類/金屬類骨水泥式彌補物	Finger joint metal / metal constrained cemented prosthesis	3
157	N.3220	限制型指關節之金屬類/聚合物類骨水泥式彌補物	Finger joint metal / polymer constrained cemented prosthesis	3
158	N.3230	限制型指關節之聚合物類彌補物	Finger joint polymer constrained prosthesis	2
159	N.3300	限制型髖關節之金屬類骨水泥式或無骨水泥式彌補物	Hip joint metal constrained cemented or uncemented prosthesis	3
160	N.3310	限制型髖關節之金屬類/聚合物類骨水泥式或無骨水泥式彌補物	Hip joint metal/polymer constrained cemented or uncemented prosthesis	2
161	N.3320	半限制型髖關節金屬類/金屬類含骨水泥式髖臼窩組件之彌補物	Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis	3
162	N.3330	半限制型髖關節金屬/金屬類含非骨水泥式髖臼窩組件之彌補物	Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis	3
163	N.3340	半限制型髖關節金屬類/複合物類骨水泥式彌補物	Hip joint metal/composite semi-constrained cemented prosthesis	2
164	N.3350	半限制型髖關節金屬類/聚合物類骨水泥式彌補物	Hip joint metal/polymer semi-constrained cemented prosthesis	2
165	N.3353	半限制型髖關節之金屬類/陶瓷類/聚合物類骨水泥或無孔塗佈無骨水泥式彌補物	Hip joint metal / ceramic / polymer semi-constrained cemented or nonporous uncemented prosthesis	2
166	N.3358	半限制型髖關節金屬類/聚合物類/金屬類多孔塗佈無骨水泥式彌補物	Hip joint metal / polymer / metal semi-constrained porous-coated uncemented proshesis	2
167	N.3360	髖關節股骨(半髖)金屬骨水泥或無骨水泥式彌補物	Hip joint femoral(hemi-hip) metallic cemented or uncemented prosthesis	2
168	N.3370	髖關節(半髖)髖臼金屬骨水泥式彌補物	Hip joint (hemi-hip) acetabular metal cemented prosthesis	3
169	N.3380	髖關節股骨(半髖)骨幹軸承金屬類/多縮醛類骨水泥式彌補物	Hip joint femoral(hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis	3

154 N.3180

Elbow joint humeral (hemi-elbow) metallic uncemented prosthesis

3

155 N.3200

Finger joint metal / metal constrained uncemented prosthesis

3

156 N.3210

Finger joint metal / metal constrained cemented prosthesis

3

157 N.3220

Finger joint metal / polymer constrained cemented prosthesis

3

158 N.3230

Finger joint polymer constrained prosthesis

2

159 N.3300

Hip joint metal constrained cemented or uncemented prosthesis

3

160 N.3310

Hip joint metal/polymer constrained cemented or uncemented prosthesis

2

161 N.3320

Hip joint metal/metal semi-constrained, with a cemented acetabular component, prosthesis

3

162 N.3330

Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

3

163 N.3340

Hip joint metal/composite semi-constrained cemented prosthesis

2

164 N.3350

Hip joint metal/polymer semi-constrained cemented prosthesis

2

165 N.3353

Translated by RegDesk AI

Hip joint metal / ceramic / polymer semi-constrained cemented or nonporous uncemented prosthesis

2

166 N.3358

Hip joint metal / polymer / metal semi-constrained porous-coated uncemented prosthesis

2

167 N.3360

Hip joint femoral(hemi-hip) metallic cemented or uncemented prosthesis

3

168 N.3370

Hip joint (hemi-hip) acetabular metal cemented prosthesis

3

169 N.3380

Hip joint femoral(hemi-hip) trunnion-bearing metal/polyacetal cemented prosthesis

3

Translated by RegDesk AI

170	N.3390	髖關節股骨(半髖)金屬類/聚合物類骨水泥或無骨水泥式彌補物	Hip joint femoral(hemi-hip) metal/polymerl cemented or uncemented prosthesis	2
171	N.3400	髖關節股骨(半髖)金屬類重鋪面骨彌補物	Hip joint femoral(hemi-hip) metallic resurfacing prosthesis	2
172	N.3410	半限制型髖關節金屬類/聚合物類重鋪面式骨水泥彌補物	Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis	3
173	N.3480	限制型膝關節股脛骨金屬類骨水泥式彌補物	Knee joint femorotibial metallic constrained cemented prosthesis	3
174	N.3490	非限制型膝關節股脛骨金屬類/複合物類骨水泥式彌補物	Knee joint femorotibial metal/composite non-constrained cemented prosthesis	2
175	N.3500	半限制型膝關節股脛骨金屬類/複合物類骨水泥式彌補物	Knee joint femorotibial metal/composite semi-constrained cemented prosthesis	2
176	N.3510	限制型膝關節股脛骨金屬類/聚合物類骨水泥式彌補物	Knee joint femorotibial metal/polymer constrained cemented prosthesis	2
177	N.3520	非限制型膝關節股脛骨金屬類/聚合物類骨水泥式彌補物	Knee joint femorotibial metal/polymer non-constrained cemented prosthesis	2
178	N.3530	半限制型膝關節股脛骨金屬類/聚合物類骨水泥式彌補物	Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis	2
179	N.3535	膝關節股脛骨(單側)金屬類/聚合物類多孔塗佈無骨水泥式彌補物	Knee joint femorotibial unicompartmental metal/polymer porous-coated uncemented prosthesis	2
180	N.3540	半限制型膝關節臏股骨聚合物類/金屬類骨水泥式彌補物	Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis	2
181	N.3550	限制型膝關節臏股脛骨聚合物類/金屬類/金屬類骨水泥式彌補物	Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis	3
182	N.3560	半限制型膝關節臏股脛骨聚合物類/金屬類/聚合物類骨水泥式彌補物	Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis	2

```

170 N.3390 Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented prosthesis 2

171 N.3400 Hip joint femoral (hemi-hip) metallic resurfacing prosthesis 2

172 N.3410 Hip joint metal/polymer semi-constrained resurfacing cemented prosthesis 3

173 N.3480 Knee joint femorotibial metallic constrained cemented prosthesis 3

174 N.3490 Knee joint femorotibial metal/composite non-constrained cemented prosthesis 2

175 N.3500 Knee joint femorotibial metal/composite semi-constrained cemented prosthesis 2

176 N.3510 Knee joint femorotibial metal/polymer constrained cemented prosthesis 2

177 N.3520 Knee joint femorotibial metal/polymer non-constrained cemented prosthesis 2

178 N.3530 Knee joint femorotibial metal/polymer semi-constrained cemented prosthesis 2

179 N.3535 Knee joint femorotibial unicompartmental metal/polymer porous-coated uncemented prosthesis 2

180 N.3540 Knee joint patellofemoral polymer/metal semi-constrained cemented prosthesis 2

181 N.3550 Knee joint patellofemorotibial polymer/metal/metal constrained cemented prosthesis 3

182 N.3560 Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis 2

```

Translated by RegDesk AI

183	N.3565	膝關節髕股骨金屬類/聚合物類多孔塗佈無骨水泥式彌補物	Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis	2
184	N.3570	膝關節股骨(半膝)金屬類無骨水泥式彌補物	Knee joint femoral (hemi-knee) metallic uncemented prosthesis	3
185	N.3580	膝關節臏骨(半膝)金屬類重鋪面無骨水泥式彌補物	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	2,3
186	N.3590	膝關節脛骨(半膝)金屬類重鋪面無骨水泥式彌補物	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	2
187	N.3640	限制型肩關節金屬類/金屬類或金屬類/聚合物類骨水泥式彌補物	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	3
188	N.3650	非限制型肩關節金屬類/聚合物類骨水泥式彌補物	Shoulder joint metal / polymer non-constrained cemented prosthesis	2
189	N.3660	半限制型肩關節金屬類/聚合物類骨水泥式彌補物	Shoulder joint metal/polymer semi-constrained cemented prosthesis	2
190	N.3670	肩關節金屬類/聚合物類非限制型或半限制型多孔塗佈無骨水泥式彌補物	Shoulder joint metal/polymer/metal nonconstrained or semiconstrained porous-coated uncemented prosthesis	2
191	N.3680	肩關節盂(半肩)金屬類骨水泥式彌補物	Shoulder joint glenoid (hemi-shoulder)metallic cemented prosthesis	3
192	N.3690	肩關節肱骨(半肩)金屬類無骨水泥式彌補物	Shoulder joint humeral (hemi-shoulder)metallic uncemented prosthesis	2
193	N.3720	限制型趾關節聚合物類彌補物	Toe joint polymer constrained prosthesis	2
194	N.3730	趾關節趾骨(半趾)聚合物類彌補物	Toe joint phalangeal (hemi-toe)polymer prosthesis	2
195	N.3750	腕關節腕半月骨聚合物類彌補物	Wrist joint carpal lunate polymer prosthesis	2
196	N.3760	腕關節腕舟狀骨聚合物類彌補物	Wrist joint carpal scaphoid polymer prosthesis	2
197	N.3770	腕關節腕多角骨聚合物類彌補物	Wrist joint carpal trapezium polymer prosthesis	2

1...	N....	Knee joint patellofemortibial metal/polymer porous-coated uncemented prosthesis	2
1...	N....	Knee joint femoral (hemi-knee) metallic uncemented prosthesis	3
1...	N....	Knee joint patellar (hemi-knee) metallic resurfacing uncemented prosthesis	2...
1...	N....	Knee joint tibial (hemi-knee) metallic resurfacing uncemented prosthesis	2
1...	N....	Shoulder joint metal/metal or metal/polymer constrained cemented prosthesis	2
1...	N....	Shoulder joint metal/polymer non-constrained cemented prosthesis	2
1...	N....	Shoulder joint metal/polymer semi-constrained cemented prosthesis	2
1...	N....	Shoulder joint metal/polymer/metal nonconstrained or semiconstrained porous-coated uncemented prosthesis	2
1...	N....	Shoulder joint glenoid (hemi-shoulder)metallic cemented prosthesis	3
1...	N....	Shoulder joint humeral (hemi-shoulder)metallic uncemented prosthesis	2
1...	N....	Toe joint polymer constrained prosthesis	2
1...	N....	Toe joint phalangeal (hemi-toe)polymer prosthesis	2
1...	N....	Wrist joint carpal lunate polymer prosthesis	2
1...	N....	Wrist joint carpal scaphoid polymer prosthesis	2
1...	N....	Wrist joint carpal trapezium polymer prosthesis	2

182

Translated by RegDesk AI

198	N.3780	限制型腕關節聚合物類彌補物	Wrist joint polymer constrained prosthesis	2
199	N.3790	限制型腕關節金屬類骨水泥式彌補物	Wrist joint metal constrained cemented prosthesis	3
200	N.3800	半限制型腕關節金屬類/聚合物類骨水泥式彌補物	Wrist joint metal/polymer semi-constrained cemented prosthesis	2
201	N.3810	腕關節尺骨(半腕)聚合物類彌補物	Wrist joint ulnar(hemi-wrist) polymer prosthesis	2
202	P.5725	可吸收式肛門直腸周邊阻隔器	Absorbable perirectal spacer	2

1...	N.3780	Wrist joint polymer constrained prosthesis	2
1...	N.3790	Wrist joint metal constrained cemented prosthesis	3
2...	N.3800	Wrist joint metal/polymer semi-constrained cemented prosthesis	2
2...	N.3810	Wrist joint ulnar(hemi-wrist) polymer prosthesis	2
2...	P.5725	Absorbable perirectal spacer	2

183

Translated by RegDesk AI

【免取得醫療器材製造許可品項】

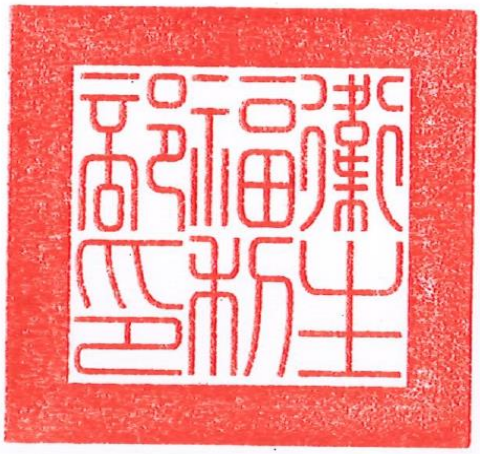
檔　　號：
保存年限：

裝

訂

線

衛生福利部　公告



發文日期：中華民國110年7月16日
發文字號：衛授食字第1101104548號
附件：免取得醫療器材製造許可品項

主旨：訂定「免取得醫療器材製造許可品項」，並自即日生效。

依據：醫療器材管理法第二十二條第二項。

公告事項：免取得醫療器材製造許可品項如附件。

部長陳時中

第一頁（共一頁）

「Items Exempted from Obtaining Medical Device Manufacturing Permit」

Ministry of Health and Welfare Announcement

Issue Date: July 16, 110th Year of the Republic of China

Document Number: Shu-Jun-Zi No. 1101104548

Attachment: Items Exempted from Obtaining Medical Device Manufacturing Permit

Subject: Establishing "Items Exempted from Obtaining Medical Device Manufacturing Permit," effective immediately.

According to: Article 22, Paragraph 2 of the Medical Device Management Law.

Announcement: The items exempted from obtaining the medical device manufacturing permit are listed in the attachment.

Minister

[Signature and Seal]

Page 1 (Total 1 Page)

184

Translated by RegDesk AI

免取得醫療器材製造許可品項

下表所列醫療器材品項未滅菌者，免取得製造許可。

序號	代碼	中文名稱	英文名稱	等級
1	A.1660	品管材料(分析與非分析)	Quality control material (assayed and unassayed)	1
2	A.2270	臨床使用的薄層色層分析系統	Thin-layer chromatography system for clinical use	1
3	B.1850	染料及化學溶液染料	Dye and chemical solution stains	1
4	C.2600	Wood氏螢光燈	Wood's fluorescent lamp	1
5	D.5220	吹氣瓶	Blow bottle	1
6	D.5280	呼吸管路支撐物	Breathing tube support	1
7	F.1820	牙科用X光片照射排列裝置	Dental x-ray exposure alignment device	1
8	F.3140	樹脂塗敷器	Resin applicator	1
9	F.3670	樹脂印模牙托材	Resin impression tray material	1
10	F.4535	牙科用鑽石器械	Dental diamond instrument	1
11	F.4565	牙科手用器械	Dental hand instrument	1
12	F.6010	研磨裝置及其附件	Abrasive device and accessories	1
13	F.6050	唾液吸收器	Saliva absorber	1
14	F.6140	咬合紙	Articulation paper	1
15	F.6200	基底塗料	Base plate shellac	1
16	F.6290	磨光劑載杯	Prophylaxis cup	1
17	F.6300	橡皮障及其附件	Rubber dam and accessories	1
18	F.6570	印模管	Impression tube	1
19	F.6870	拋棄式塗氟用牙托	Disposable fluoride tray	1
20	F.6880	成形印模牙托	Preformed impression tray	1
21	F.6890	口內牙科用臘	Intraoral dental wax	1
22	G.1100	聽力檢查耳機軟墊	Earphone cushion for audiometric testing	1
23	G.3540	聽小骨置換物修正用器械	Prosthesis modification instrument for ossicular replacement surgery	1
24	G.4350	耳鼻喉光纖光源及載具	Ear, nose, and throat fiberoptic light source and carrier	1
25	G.4770	耳鏡	Otoscope	1
26	G.5220	耳鼻喉佈施藥裝置及其搭配使用之物質	Ear, nose, and throat drug administration device and contained substance	1
27	G.5800	鼻外固定板	External nasal splint	1
28	H.5210	手動式灌腸組套	Enema kit	1
29	H.5250	尿液收集器及其附件	Urine collector and accessories	1
30	H.5900	造口術用袋及其附件	Ostomy pouch and accessories	1
31	H.5970	疝脫支撐器	Hernia support	1
32	I.1800	檢查鏡及其附件	Speculum and accessories	1
33	I.3800	體外美容用修復彌補物	External aesthetic restoration prosthesis	1
34	I.3910	非膨脹式四肢用夾板	Noninflatable extremity splint	1
35	I.4025	疤痕處理矽膠產品	Silicone scar management product	1
36	I.4160	外科手術用照相機及其附件	Surgical camera and accessories	1
37	I.4700	外科顯微鏡及其附件	Surgical microscope and accessories	1
38	I.4730	外科用皮膚去油劑或去黏劑	Surgical skin degreaser or adhesive tape solvent	1
39	I.5900	非充氣式止血帶	Nonpneumatic tourniquet	1
40	J.5075	彈性繃帶	Elastic bandage	1
41	J.5120	手動可調整式病床	Manual adjustable hospital bed	1
42	J.5150	非動力式治療床墊	Nonpowered flotation therapy mattress	1

ENGLISH TRANSLATION · Orig. Pg 188

Medical Device Manufacturing Permit Exemption Items

Medical devices listed below are exempted from manufacturing permits.

N...	Code	Chinese Name	English Name	Gr...
1	A.1...	□□□□□□(□□□□□□)	Quality control material (assayed and unassayed)	1
2	A.2...	□□□□□□□□□□□□□..	Thin-layer chromatography system for clinical use	1
3	B.1...	□□□□□□□□□	Dye and chemical solution stains	1
4	C.2...	□□□□□	Wood's fluorescent lamp	1
5	D.5...	□□	Blow bottle	1
6	D.5...	□□□□□□□	Breathing tube support	1
7	F.1...	□□□X□□□□□□□□	Dental x-ray exposure alignment device	1
8	F.3...	□□□□□	Resin applicator	1
9	F.3...	□□□□□□	Resin impression tray material	1
10	F.4...	□□□□□□□□	Dental diamond instrument	1
11	F.4...	□□□□□□	Dental hand instrument	1
12	F.6...	□□□□□□□□	Abrasive device and accessories	1
13	F.6...	□□□	Saliva absorber	1
14	F.6...	□□□	Articulation paper	1
15	F.6...	□□□□	Base plate shellac	1
16	F.6...	□□□	Prophylaxis cup	1
17	F.6...	□□□□□□□	Rubber dam and accessories	1
18	F.6...	□□□	Impression tube	1
19	F.6...	□□□□□□□	Disposable fluoride tray	1
20	F.6...	□□□□□	Preformed impression tray	1
21	F.6...	□□□□□□	Intraoral dental wax	1
22	G.1...	□□□□□□□	Earphone cushion for audiometric testing	1
23	G.4...	□□□□□□□□□□□□	Prosthesis modification instrument for ossicular replacement surgery	1
24	G.4...	□□□□□□□□□□□	Ear, nose, and throat fiberoptic light source and carrier	1
25	G.4...	□□□	Otoscope	1
26	G.5...	□□□□□□□□□□□□□	Ear, nose, and throat drug administration device and contained substance	1
27	G.5...	□□□□□□	External nasal splint	1
28	H.5...	□□□□□	Enema kit	1
29	H.5...	□□□□□□□□□	Urine collector and accessories	1
30	H.5...	□□□□□□□□	Ostomy pouch and accessories	1
31	H.5...	□□□□□	Hernia support	1
32	I.1...	□□□□□□□	Speculum and accessories	1
33	I.3...	□□□□□□□□□	External aesthetic restoration prosthesis	1
34	L.3...	□□□□□□□□	Noninflatable extremity splint	1
35	I.4...	□□□□□□□□	Silicone scar management product	1
36	I.4...	□□□□□□□□□□□□	Surgical camera and accessories	1

ENGLISH TRANSLATION · Orig. Pg 188 (cont.)

37	**I.4700**	□□□□□□□□□□	**Surgical microscope and accessories**	**1**
38	I.4730	□□□□□□□□□□□□□	Surgical skin degreaser or adhesive tape solvent	1
39	I.5900	□□□□□□□	Nonpneumatic tourniquet	1
40	J.5075	□□□□	Elastic bandage	1
41	J.5120	□□□□□□□	Manual adjustable hospital bed	1
42	J.5150	□□□□□□□□□□	Nonpowered flotation therapy mattress	1

Translated by RegDesk AI

43	J.5160	醫療用束帶	Therapeutic medical binder	1
44	J.5210	血管內導管固定裝置	Intravascular catheter securement device	1
45	J.5240	醫療用黏性膠帶及黏性繃帶	Medical adhesive tape and adhesive bandage	1
46	J.5270	新生兒用眼罩	Neonatal eye pad	1
47	J.5300	醫療用吸收纖維	Medical absorbent fiber	1
48	J.5780	醫用輔助襪	Medical support stocking	1
49	J.5820	治療用陰囊支撐器	Therapeutic scrotal support	1
50	J.6025	吸收性尖端塗藥器	Absorbent tipped applicator	1
51	J.6230	壓舌板	Tongue depressor	1
52	J.6375	病患用潤滑劑	Patient lubricant	1
53	J.6430	液體藥物給藥器	Liquid medication dispenser	1
54	J.6450	皮膚壓力保護器	Skin pressure protectors	1
55	J.6785	手動病患輸送裝置	Manual patient transfer device	1
56	J.6900	手提式擔架	Hand-carried stretcher	1
57	J.6960	灌洗注射筒	Irrigating syringe	1
58	J.6970	液晶靜脈定位器	Liquid crystal vein locator	1
59	J.6980	靜脈固定器	Vein stabilizer	1
60	K.1200	兩點式判讀儀	Two-point discriminator	1
61	K.1500	觸覺計	Esthesiometer	1
62	K.1525	調音叉	Tuning fork	1
63	K.4190	夾成形/切割器械	Clip forming/cutting instrument	1
64	K.4200	去夾器械	Clip removal instrument	1
65	L.5900	治療用陰道灌洗器	Therapeutic vaginal douche apparatus	1
66	M.1090	黃斑部色素光學密度儀	Haidinger brush	1
67	M.1140	眼科用椅	Ophthalmic chair	1
68	M.1200	眼球運動鼓狀器	Optokinetic drum	1
69	M.1320	穹窿鏡	Fornixscope	1
70	M.1350	角膜鏡	Keratoscope	1
71	M.1375	Bagolini鏡片	Bagolini lens	1
72	M.1380	診斷用聚光鏡片	Diagnostic condensing lens	1
73	M.1390	診斷用彈性Fresnel鏡片	Flexible diagnostic Fresnel lens	1
74	M.1395	診斷用Hruby眼底鏡片	Diagnostic Hruby fundus lens	1
75	M.1400	瑪賽氏鏡	Maddox lens	1
76	M.1405	眼科試驗鏡片組	Ophthalmic trial lens set	1
77	M.1410	眼科試驗鏡片夾	Ophthalmic trial lens clip	1
78	M.1460	立體感測量器	Stereopsis measuring instrument	1
79	M.1605	視野鏡	Perimeter	1
80	M.1650	眼科用棒狀稜鏡	Ophthalmic bar prism	1
81	M.1655	眼科用Fresnel稜鏡(壓貼鏡片)	Ophthalmic Fresnel prism	1
82	M.1665	眼科旋轉稜鏡	Ophthalmic rotary prism	1
83	M.1680	眼科用投影機	Ophthalmic projector	1
84	M.1700	瞳孔計	Pupillometer	1
85	M.1750	視網膜檢影鏡架	Skiascopic rack	1
86	M.1790	近點尺	Nearpoint ruler	1
87	M.1810	切線幕(視野計)	Tangent screen (campimeter)	1
88	M.1870	立體鏡	Stereoscope	1
89	M.1905	眼球震顫帶	Nystagmus tape	1
90	M.1910	視覺分離試驗系統	Spectacle dissociation test system	1

43 J5160 Therapeutic medical binder 1

44 J5210 Intravascular catheter securement device 1

45 J5240 Medical adhesive tape and adhesive bandage 1

46 J5270 Neonatal eye pad 1

47 J5300 Medical absorbent fiber 1

48 J5720 Medical support stocking 1

49 J5820 Therapeutic scrotal support 1

50 J6025 Absorbent tipped applicator 1

51 J6230 Tongue depressor 1

52 J6375 Patient lubricant 1

53 J6430 Liquid medication dispenser 1

54 J6460 Skin pressure protectors 1

55 J6785 Manual patient transfer device 1

56 J6900 Hand-carried stretcher 1

57 J6960 Irrigating syringe 1

58 J6970 Liquid crystal vein locator 1

59 J6980 Vein stabilizer 1

60 K1200 Two-point discriminator 1

61 K1500 Esthesiometer 1

62 K1525 Tuning fork 1

63 K4100 Clip forming/cutting instrument 1

64 K4200 Clip removal instrument 1

65 L5900 Therapeutic vaginal douche apparatus 1

66 M1090 Haidinger brush 1

67 M1140 Ophthalmic chair 1

68 M1200 Optokinetic drum 1

69 M1320 Fornixscope 1

70 M1350 Keratoscope 1

71 M1375 Bagolini lens 1

72 M1380 Diagnostic condensing lens 1

73 M1390 Flexible diagnostic Fresnel lens 1

74 M1395 Diagnostic Hruby fundus lens 1

75 M1400 Maddox lens 1

76 M1405 Ophthalmic trial lens set 1

Translated by RegDesk AI

77 M1410 Ophthalmic trial lens clip 1

78 M1460 Stereopsis measuring instrument 1

79 M1605 Perimeter 1

80 M1650 Ophthalmic bar prism 1

81 M1655 Ophthalmic Fresnel prism 1

82 M1665 Ophthalmic rotary prism 1

83 M1680 Ophthalmic projector 1

84 M1700 Pupillometer 1

85 M1750 Skiascopic rack 1

86 M1790 Nearpoint ruler 1

87 M1810 Tangent screen (campimeter) 1

88 M1870 Stereoscope 1

89 M1905 Nystagmus tape 1

90 M1910 Spectacle dissociation test system 1

2

Translated by RegDesk AI

91	M.1945	透照器	Transilluminator	1
92	M.4335	手術用頭燈	Operating headlamp	1
93	M.4750	眼科用眼罩	Ophthalmic eye shield	1
94	M.4770	眼科用手術眼鏡(放大鏡)	Ophthalmic operating spectacles (loupes)	1
95	M.5600	上眼瞼下垂支持器	Ptosis crutch	1
96	M.5844	矯正鏡片	Corrective spectacle lens	1
97	N.1250	非動力式肌力計	Nonpowered dynamometer	1
98	N.1520	非動力式測角計	Nonpowered goniometer	1
99	N.5850	非動力式骨科牽引器及配件	Nonpowered orthopedic traction apparatus and accessories	1
100	N.5890	非侵入式牽引組件	Noninvasive traction component	1
101	N.5940	石膏類產品	Cast component	1
102	N.5980	手動式打石膏及拆石膏器械	Manual cast application and removal instrument	1
103	O.0006	連續式被動關節活動器	Continuous Passive Motion Device	1
104	O.3025	義肢及裝具用附件	Prosthetic and orthotic accessory	1
105	O.3075	醫療用手杖	Cane	1
106	O.3150	醫療用枴杖	Crutch	1
107	O.3175	浮動坐墊	Flotation cushion	1
108	O.3410	體外肢體裝具用組件	External limb orthotic component	1
109	O.3420	體外肢體義肢用組件	External limb prosthetic component	1
110	O.3475	肢體裝具	Limb orthosis	1
111	O.3490	軀幹裝具	Truncal orthosis	1
112	O.3520	治療檯	Plinth	1
113	O.3640	手臂吊帶	Arm sling	1
114	O.3665	先天性髖關節移位外展夾板	Congenital hip dislocation abduction splint	1
115	O.3675	丹尼布朗夾板	Denis Brown splint	1
116	O.3750	機械式治療檯	Mechanical table	1
117	O.3825	機械式助行器	Mechanical walker	1
118	O.5125	非動力式坐浴	Nonpowered sitz bath	1
119	O.5700	醫療用冷敷裝置	Cold pack	1
120	O.5710	醫療用可丟棄式的冷熱敷包	Hot or cold disposable pack	1
121	O.5720	醫療用水循環式冷熱敷包	Water circulating hot or cold pack	1
122	O.5730	醫療用濕熱敷包	Moist heat pack	1
123	O.5925	牽引用附件	Traction accessory	1
124	P.1920	放射線造影頭部固定器	Radiographic head holder	1
125	P.6500	個人用防護罩	Personnel protective shield	1

91 M.1945 Transilluminator 1

92 N.4335 Operating headlamp 1

93 M.4750 Ophthalmic eye shield 1

94 M.4770 Ophthalmic operating spectacles (loupes) 1

95 M.5600 Ptosis crutch 1

96 M.5844 Corrective spectacle lens 1

97 N.1250 Nonpowered dynamometer 1

98 N.1250 Nonpowered goniometer 1

99 N.5850 Nonpowered orthopedic traction apparatus and accessories 1

100 N.5890 Noninvasive traction component 1

101 N.5940 Cast component 1

102 N.5980 Manual cast application and removal instrument 1

103 O.0006 Continuous Passive Motion Device 1

104 O.3025 Prosthetic and orthotic accessory 1

105 O.3075 Cane 1

106 O.3150 Crutch 1

107 O.3175 Flotation cushion 1

108 O.3410 External limb orthotic component 1

109 O.3420 External limb prosthetic component 1

110 O.3475 Limb orthosis 1

111 O.3490 Truncal orthosis 1

112 O.3520 Plinth 1

113 O.3640 Arm sling 1

114 O.3665 Congenital hip dislocation abduction splint 1

115 O.3675 Denis Brown splint 1

116 O.3750 Mechanical table 1

117 O.3825 Mechanical walker 1

118 O.5125 Nonpowered sitz bath 1

119 O.5700 Cold pack 1

120 O.5710 Hot or cold disposable pack 1

121 O.5720 Water circulating hot or cold pack 1

122 O.5730 Moist heat pack 1

123 O.5925 Traction accessory 1

124 P.1920 Radiographic head holder 1

Translated by RegDesk AI

125 P.6500 Personnel protective shield 1

187

Translated by RegDesk AI

【醫療器材管理法第二十四條應建立醫療器材優良運銷系統之醫療器材品項及其販賣業者】

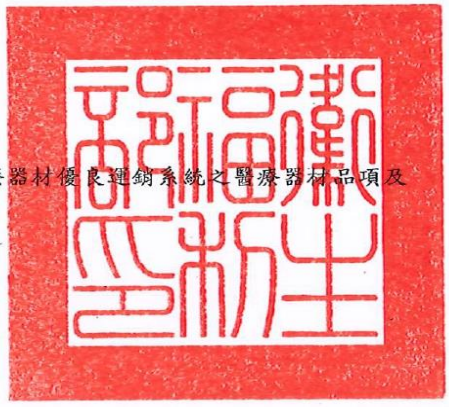
檔　　號：
保存年限：

裝

訂

線

衛生福利部　公告



發文日期：中華民國110年3月18日
發文字號：衛授食字第1091107544號
附件：「醫療器材管理法第二十四條應建立醫療器材優良運銷系統之醫療器材品項及其販賣業者」之品項清單乙份

主旨：訂定「醫療器材管理法第二十四條應建立醫療器材優良運銷系統之醫療器材品項及其販賣業者」，自中華民國一百十二年五月一日生效。

依據：「醫療器材管理法」第二十四條第一項

公告事項：訂定「醫療器材管理法第二十四條應建立醫療器材優良運銷系統之醫療器材品項及其販賣業者」，領有附件品項清單許可證之醫療器材販賣業者及其授權輸入之醫療器材販賣業者，應建立醫療器材優良運銷系統，符合醫療器材優良運銷準則，並報中央主管機關檢查合格，取得運銷許可。

部長陳時中

第一頁（共一頁）

In accordance with Article 24 of the Medical Device Management Act, an efficient distribution system for medical devices and their related business operators should be established.

Ministry of Health and Welfare Announcement

Document Date: March 18, 2021

Document Number: Wei-Bu-No. 1091107544

Attachment: In accordance with Article 24 of the Medical Device Management Act, an efficient distribution system for medical devices should be established.

Announcement by: Minister Chen Shih-Chung

Subject: Establishment of an efficient distribution system for medical devices and their related business operators, effective from May 1, 2021.

According to: Article 24, Paragraph 1, of the Medical Device Management Act

Announcement: It is prescribed according to Article 24, Paragraph 1, of the Medical Device Management Act, that an efficient distribution system for medical devices and their related business operators should be established. Manufacturers or importers of medical devices listed in the attached inventory shall enter the distribution system for medical devices and obtain a permit for the products from the relevant authorities. They must comply with the regulations regarding the efficient distribution system for medical devices. After passing the inspection by the central authority, an operating permit will be issued.

Minister of Health and Welfare,

Chen Shih-Chung

Page 1 of 1

Translated by RegDesk AI

醫療器材管理法第二十四條應建立醫療器材優良運銷系統之醫療器材品項及其販賣業者之品項清單

項次	分類分級代碼	等級	品名
1	A.1155	3	人類絨毛膜促性腺激素試驗系統
2	B.1860	3	免疫病理組織化學試劑與套組
3	B.4020	3	分析特定試劑
4	C.0004	3	人類乳突瘤病毒血清試劑
5	C.2420	3	淋病的氧化酵素篩檢試驗
6	C.3290	3	奈瑟氏淋病雙球菌抗體試驗
7	C.3305	3	單純皰疹病毒血清分析
8	E.0001	3	心血管支架
9	E.0005	3	經皮穿刺冠狀動脈導管
10	E.0006	3	血管內移植系統
11	E.3300	3	動脈栓塞裝置
12	E.3535	3	主動脈弓內氣球擴張及控制系統
13	E.3545	3	心室血管繞道術(輔助)裝置
14	E.3610	3	植入式心律器之脈搏產生器
15	E.3680	3	心血管用永久或暫時性之心律調節器電極
16	E.3925	3	心臟瓣膜置換物
17	F.3930	3	牙槽修復材料
18	F.3960	3	下顎髁彌補物
19	G.0001	3	人工耳蝸植入器
20	H.5270	3	植入式電子排尿自制裝置
21	H.5280	3	植入式機械/水壓式排尿自制裝置
22	H.5540	3	血液通路裝置及其附件
23	I.0002	3	膠原蛋白植入劑
24	I.0007	3	玻尿酸植入物
25	I.3530	3	生理食鹽水充填之乳房彌補物
26	I.3540	3	矽膠充填之乳房彌補物
27	I.4010	3	組織黏著劑
28	I.4490	3	可吸收性止血劑及敷料
29	K.5820	3	植入式小腦刺激器

List of Items and Their Providers for Establishing a Medical Device Quality Management System in Accordance with Article 24 of the Medical Device Management Law

It...	Classification Code	Gra...	Name of Item
1	A.1155	3	Human Fetal Reproductive Health System
2	B.1860	3	Immunotherapy Tissue Organ Testing and Group
3	B.4020	3	Analysis Test Equipment
4	C.0004	3	Human Nasal Surgery Tumor Detection Kit
5	C.2420	3	Dissolution Chemical Solution Precision Analysis
6	C.3290	3	Hemostatic Measures Physical Conditioning
7	C.3305	3	Single Molecule Disease Blood Analysis
8	E.0001	3	Cardiovascular Record System
9	E.0005	3	Spinal Vertebral Rehabilitation Cannula
10	E.0006	3	Blood Analysis System
11	E.3300	3	Animal Testing Equipment
12	E.3535	3	Automatic Infusion Speed Control System
13	E.3545	3	Cardiopulmonary Resuscitation Manipulation Instructor
14	E.3610	3	Implantable Organ Growth Stimulation Device
15	E.3680	3	Heart Pacing Long-Term Monitoring Power Board
16	E.3925	3	Cardiopulmonary Function Accessories
17	F.3930	3	Dental Repair Materials
18	F.3960	3	Lower Jaw Function Support
19	G.0001	3	Human Ear Implant Perfusion
20	H.5270	3	Implantable Electronic Auxiliary Device
21	H.5280	3	Implantable Dialysis Membrane Pulmonary Artificial Apparatus
22	H.5540	3	Blood Circulation Equipment and Accessories
23	I.0002	3	Thoracic Injection Syringe
24	I.0007	3	Glass Urine Collection Tube
25	I.3530	3	Physiological Stimulation Nasal Cavity Planning Supplement
26	I.3540	3	Silica Gel Ear Cavity Filling Supplement
27	I.4010	3	Biothermal Analgesic
28	I.4490	3	Hemostatic Materials and Accessories
29	K.5820	3	Implantable Small Intestine Repair Device

Translated by RegDesk AI

30	K.5830	3	植入式膈膜/膈神經刺激器
31	K.5840	3	疼痛舒緩用植入式大腦內/皮質下刺激器
32	K.5880	3	疼痛舒緩用植入式脊髓刺激器
33	K.5950	3	人工栓塞裝置
34	L.0004	3	可吸收性防沾黏材質
35	L.5360	3	子宮內避孕器及放置器
36	L.5980	3	經陰道骨盆腔器官脫垂治療用手術網片
37	M.3600	3	人工水晶體
38	M.4270	3	眼內充填用氣體
39	M.4275	3	眼內充填用液體
40	N.0003	3	關節腔玻尿酸植入物
41	N.3030	2	單一或多重之金屬類骨固定裝置及附件
42	N.3070	3	椎弓螺釘系統
43	N.3080	3	椎體間融合裝置
44	N.3300	3	限制型髖關節之金屬類骨水泥式或無骨水泥式彌補物
45	N.3320	3	半限制型髖關節金屬類/金屬類含骨水泥式髖臼窩組件之彌補物

30 K.5830 3 Implantable Drug/Neurotoxin Injectable Device

31 K.5840 3 Pain Relief Auxiliary Implantable/Delivery Device Injectables

32 K.5880 3 Pain Relief Auxiliary Implantable Drug Injectables

33 K.5950 3 Artificial Dura Mater

34 L.0004 3 Absorbable Hemostatic Material

35 L.5360 3 For Nasal Cavity Absorbable Hemostatic Dressing

36 L.5980 3 Surgical Suspending Clamp for Treating Carpal Tunnel Syndrome

37 M.3600 3 Artificial Tear

38 M.4270 3 Soft Contact Lens

39 M.4275 3 Soft Contact Lens Solution

40 N.0003 2 Tendon and Ligament Prosthetic Material

41 N.3030 2 Multiple Trauma and Musculoskeletal Soft Tissue Fixation Systems and Accessories

42 N.3070 3 Spinal Internal Fixation System

43 N.3080 3 Spinal External Fixation System

44 N.3300 3 Non-limitation Material for Internal Fixation of Bone Fractures with Calcium Phosphate Cement

45 N.3320 3 Semi-limited Internal Fixation Bone Plate with Calcium Phosphate or Bone Cement Injectable Material to Compensate for Fisherman's Deficiency

190

Translated by RegDesk AI

【應以登錄方式取得上市許可之醫療器材品項】

檔　　號：
保存年限：

裝

訂

線

衛生福利部　公告



發文日期：中華民國110年4月13日
發文字號：衛授食字第1101602280號
附件：「應以登錄方式取得上市許可之醫療器材品項」。

主旨：訂定「應以登錄方式取得上市許可之醫療器材品項」，並自中華民國一百十年十月一日生效。

依據：醫療器材管理法第二十五條第一項。

部長陳時中

第一頁（共一頁）

□Medical Device Items That Should Obtain Market Approval Through Registration□

Number:

Valid Year:

Ministry of Health and Welfare Announcement

Issue Date: April 13, 2021

Document Number: Wei-Shu-Yi-Zi No. 1101602280

Attachment: "Medical Device Items That Should Obtain Market Approval Through Registration"

Subject: Establishment of "Medical Device Items That Should Obtain Market Approval Through Registration" effective from November 1, Republic of China Year 110.

According to: Article 25, Paragraph 1 of the Medical Device Management Act.

Minister Chen Shih-chung

Page 1 (of 1)

Translated by RegDesk AI

應以登錄方式取得上市許可之醫療器材品項

序號	代碼	中文名稱	英文名稱	等級
1	A.2150	臨床使用的連續流動式多項化學分析儀	Continuous flow sequential multiple chemistry analyzer for clinical use	1
2	A.2160	臨床使用的個別式光度量測化學分析儀	Discrete photometric chemistry analyzer for clinical use	1
3	A.2260	臨床使用的高壓液相層析儀	High pressure liquid chromatography system for clinical use	1
4	A.2300	臨床使用的色度計、光度計或分光光度計	Colorimeter, photometer, or spectrophotometer for clinical use	1
5	A.2485	臨床使用的電泳設備	Electrophoresis apparatus for clinical use	1
6	A.2500	臨床使用的酵素分析儀	Enzyme analyzer for clinical use	1
7	A.2560	臨床使用的螢光儀	Fluorometer for clinical use	1
8	A.2900	自動尿液分析系統	Automated urinalysis system	1
9	B.1850	染料及化學溶液染料	Dye and chemical solution stains	1
10	B.9195	血液混合器及血液重量分析裝置	Blood mixing devices and blood weighing devices	1
11	B.9275	體外診斷用血庫離心機	Blood bank centrifuge for in vitro diagnostic use	1
12	C.4540	免疫比濁計	Immunonephelometer equipment	1
13	D.2320	無補償式管流量計	Uncompensated thorpe tube flowmeter	1
14	D.2340	補償式管流量計	Compensated thorpe tube flowmeter	1
15	D.2610	氣體壓力計	Gas pressure gauge	1
16	D.2700	壓力調節器	Pressure regulator	1
17	F.3140	樹脂塗敷器	Resin applicator	1
18	F.3661	CAD/CAM光學取模系統	Optical Impression Systems for CAD/CAM	1
19	F.3670	樹脂印模牙托材	Resin impression tray material	1
20	F.6010	研磨裝置及其附件	Abrasive device and accessories	1
21	F.6050	唾液吸收器	Saliva absorber	1
22	F.6140	咬合紙	Articulation paper	1
23	F.6290	磨光劑載杯	Prophylaxis cup	1
24	F.6300	橡皮障及其附件	Rubber dam and accessories	1
25	F.6570	印模管	Impression tube	1
26	F.6880	成形印模牙托	Preformed impression tray	1
27	F.6890	口內牙科用臘	Intraoral dental wax	1
28	H.1400	胃的酸鹼度電極	Stomach pH electrode	1
29	H.5970	疝脫支撐器	Hernia support	1
30	I.3800	體外美容用修復彌補物	External aesthetic restoration prosthesis	1
31	I.3910	非膨脹式四肢用夾板	Noninflatable extremity splint	1
32	J.5100	交流電力可調整式病床	AC-powered adjustable hospital bed	1
33	J.5120	手動可調整式病床	Manual adjustable hospital bed	1
34	J.5140	小兒病床	Pediatric hospital bed	1

Serial No.	Code	Chinese Name	English Name	Class
1	**A.2150**	**Continuous flow sequential multiple chemistry analyzer for clinical use**		**1**
2	A.2160	Discrete photometric chemistry analyzer for clinical use		1
3	A.2260	High pressure liquid chromatography system for clinical use		1
4	A.2300	Colorimeter, photometer, or spectrophotometer for clinical use		1
5	A.2485	Electrophoresis apparatus for clinical use		1
6	A.2500	Enzyme analyzer for clinical use		1
7	A.2560	Fluorometer for clinical use		1
8	A.2900	Automated urinalysis system		1
9	B.1850	Dye and chemical solution stains		1
10	B.9195	Blood mixing devices and blood weighing devices		1
11	B.9275	Blood bank centrifuge for in vitro diagnostic use		1
12	C.4540	Immunonephelometer equipment		1
13	D.2320	Uncompensated thorpe tube flowmeter		1
14	D.2340	Compensated thorpe tube flowmeter		1
15	D.2610	Gas pressure gauge		1
16	D.2700	Pressure regulator		1
17	F.3140	Resin applicator		1
18	F.3661	Optical Impression Systems for CAD/CAM		1
19	F.3670	Resin impression tray material		1
20	F.6010	Abrasive device and accessories		1
21	F.6050	Saliva absorber		1
22	F.6140	Articulation paper		1
23	F.6290	Prophylaxis cup		1
24	F.6300	Rubber dam and accessories		1
25	F.6570	Impression tube		1
26	F.6880	Preformed impression tray		1
27	F.6890	Intraoral dental wax		1
28	H.1400	Stomach pH electrode		1
29	H.5970	Hernia support		1
30	I.3880	External aesthetic restoration prosthesis		1
31	I.3910	Noninflatable extremity splint		1
32	J.5100	AC-powered adjustable hospital bed		1
33	J.5120	Manual adjustable hospital bed		1
34	J.5140	Pediatric hospital bed		1

Translated by RegDesk AI

序號	代碼	中文名稱	英文名稱	等級
35	J.5150	非動力式治療床墊	Nonpowered flotation therapy mattress	1
36	J.5160	醫療用束帶	Therapeutic medical binder	1
37	J.6450	皮膚壓力保護器	Skin pressure protectors	1
38	J.6785	手動病患輸送裝置	Manual patient transfer device	1
39	J.6900	手提式擔架	Hand-carried stretcher	1
40	M.1140	眼科用椅	Ophthalmic chair	1
41	M.1350	角膜鏡	Keratoscope	1
42	M.1460	立體感測量器	Stereopsis measuring instrument	1
43	M.1605	視野鏡	Perimeter	1
44	M.1700	瞳孔計	Pupillometer	1
45	M.1760	自動眼科驗光機	Ophthalmic refractometer	1
46	M.1770	手動式驗光儀	Manual refractor	1
47	M.1870	立體鏡	Stereoscope	1
48	M.4770	眼科用手術眼鏡(放大鏡)	Ophthalmic operating spectacles (loupes)	1
49	N.5850	非動力式骨科牽引器及配件	Nonpowered orthopedic traction apparatus and accessories	1
50	O.1575	測力板	Force-measuring platform	1
51	O.1925	等速肌力試驗評估系統	Isokinetic Testing and Evaluation System	1
52	O.3075	醫療用手杖	Cane	1
53	O.3150	醫療用枴杖	Crutch	1
54	O.3410	體外肢體裝具用組件	External limb orthotic component	1
55	O.3420	體外肢體義肢用組件	External limb prosthetic component	1
56	O.3475	肢體裝具	Limb orthosis	1
57	O.3490	軀幹裝具	Truncal orthosis	1
58	O.3520	治療檯	Plinth	1
59	O.3640	手臂吊帶	Arm sling	1
60	O.5125	非動力式坐浴	Nonpowered sitz bath	1
61	O.5700	醫療用冷敷裝置	Cold pack	1
62	O.5730	醫療用濕熱敷包	Moist heat pack	1
63	O.5740	動力式熱敷墊	Powered heating pad	1
64	O.5925	牽引用附件	Traction accessory	1
65	P.1320	核醫攝取探頭	Nuclear uptake probe	1
66	P.1700	診斷用X光機高壓產生器	Diagnostic x-ray high voltage generator	1
67	P.1920	放射線造影頭部固定器	Radiographic head holder	1
68	P.1980	放射線檯	Radiographic table	1

N...	Co...	Chinese Name	English Name	Cl...
35	J....	Nonpowered flotation therapy mattress	Nonpowered flotation therapy mattress	1
36	J....	Therapeutic medical binder	Therapeutic medical binder	1
37	J....	Skin pressure protectors	Skin pressure protectors	1
38	J....	Manual patient transfer device	Manual patient transfer device	1
39	J....	Hand-carried stretcher	Hand-carried stretcher	1
40	M....	Ophthalmic chair	Ophthalmic chair	1
41	M....	Keratoscope	Keratoscope	1
42	M....	Stereopsis measuring instrument	Stereopsis measuring instrument	1
43	M....	Perimeter	Perimeter	1
44	M....	Pupillometer	Pupillometer	1
45	M....	Ophthalmic refractometer	Ophthalmic refractometer	1
46	M....	Manual refractor	Manual refractor	1
47	M....	Stereoscope	Stereoscope	1
48	M....	Ophthalmic operating spectacles (loupes)	Ophthalmic operating spectacles (loupes)	1
49	N....	Nonpowered orthopedic traction apparatus and	Nonpowered orthopedic traction apparatus and accessories	1
50	O....	Force-measuring platform	Force-measuring platform	1
51	O....	Isokinetic Testing and Evaluation System	Isokinetic Testing and Evaluation System	1
52	O....	Cane	Cane	1
53	O....	Crutch	Crutch	1
54	O....	External limb orthotic component	External limb orthotic component	1
55	O....	External limb prosthetic component	External limb prosthetic component	1
56	O....	Limb orthosis	Limb orthosis	1
57	O....	Truncal orthosis	Truncal orthosis	1
58	O....	Plinth	Plinth	1
59	O....	Arm sling	Arm sling	1
60	O....	Nonpowered sitz bath	Nonpowered sitz bath	1
61	O....	Cold pack	Cold pack	1
62	O....	Moist heat pack	Moist heat pack	1
63	O....	Powered heating pad	Powered heating pad	1
64	O....	Traction accessory	Traction accessory	1
65	P....	Nuclear uptake probe	Nuclear uptake probe	1
66	P....	Diagnostic x-ray high voltage generator	Diagnostic x-ray high voltage generator	1
67	P....	Radiographic head holder	Radiographic head holder	1
68	P....	Radiographic table	Radiographic table	1

Translated by RegDesk AI

【特定醫療器材品項應符合之規格、檢驗方法及性能】

檔　　號：
保存年限：

衛生福利部　公告

發文日期：中華民國112年8月15日
發文字號：衛授食字第1121606039號
附件：「特定醫療器材品項應符合之規格、檢驗方法及性能」

裝

主旨：訂定「特定醫療器材品項應符合之規格、檢驗方法及性能」，並自中華民國一百十三年九月一日生效。

訂

依據：醫療器材管理法第三十條第二項。

公告事項：訂定「特定醫療器材品項應符合之規格、檢驗方法及性能」如附件。

部長 薛瑞元

線

第1頁　共1頁

□Specifications, Testing Methods, and Capabilities for Specific Medical Device Item Compliance□

Ministry of Health and Welfare Announcement

Document date: Republic of China, August 15, Year 112

Document number: Shu-Chi-Tzu No. 1121600398

Subject: "Specifications, Testing Methods, and Capabilities for Specific Medical Device Item Compliance"

Basis: Medical Device Management Act Article 36, Paragraph 2

Announcement: Establishment of "Specifications, Testing Methods, and Capabilities for Specific Medical Device Item Compliance" as per attachment.

Minister

Translated by RegDesk AI

特定醫療器材品項應符合之規格、檢驗方法及性能

分級分類代碼	品項名稱	等級	產品種類	規格、檢驗方法及性能
G.3300	助聽器	一	空氣傳導性助聽器	依產品性能應符合 IEC 60601-1(電性安全)、IEC 60601-1-2(電磁相容性)、ANSI S3.22(電聲學性能)或其他具等同性國際標準之相關性能規格要求
I.4040	醫療用衣物	一	拋棄式隔離衣	依產品性能應符合 CNS 14798(T5019) P1 等級或其他具等同性之國際標準中對於「靜水壓」及「衝擊穿透」之性能規格要求
		一、二	醫用面(口)罩	其屬有色或染色者應符合 CNS 14774 對於「游離甲醛」、「禁用之偶氮色料含量」、「可遷移性螢光物質」之品質規格要求
O.3825	機械式助行器	一	無配件之助行器	依產品性能應符合 CNS 15037-1、ISO 11199-1 或其他具等同性之國際標準中對於「疲勞測試」、「靜態負載測試」、「靜態腳管強度測試」、「前傾穩定性測試」、「後傾穩定性測試」及「側傾穩定性測試」之性能規格要求
			帶輪助行器	依產品性能應符合 CNS 15037-2、ISO 11199-2 或其他具等同性之國際標準中對於「前傾穩定性測試」、「後傾穩定性測試」、「側傾穩定性測試」、「煞車測試」、「握套測試」、「橡膠腳端測試」、「椅座測試」、「靜態負載測試」、「疲勞測試」、「最終檢驗」之性能規格要求
			附前臂支撐桌助行器	依產品性能應符合 CNS 15037-3、ISO 11199-3 或其他具等同性之國際標準中對於「前傾穩定性測試」、「後傾穩定性測試」、「側傾穩定性測試」、「煞車測試」、「休息用椅座測試」、「靜態強度測試」、「疲勞測試」、「最終測試」之性能規格要求

註：除上開規定外，其產品性能規格亦須符合醫療器材分類分級管理辦法附表品項鑑別規定。

Specifications and Testing Methods for Compliance of Specific Medical Devices

C... C...	I... N...	G...	Main Purpose	Specifications and Testing Methods
G. 3...	H... A...	–	Air-conduction Hearing Aids	Comply with performance specifications such as IEC 60601-1 (electrical safety), IEC 60601-1-2 (electromagnetic compatibility), ANSI S3.22 (electroacoustic performance), or corresponding standard or performance specification requirements.
I. 4...	M.. F... M..	–	Surgical Masks	Comply with performance specifications such as CNS 14798 (T5019) P1 protection level or corresponding international standard specifications, and “Particle Filtration Efficiency” related specification requirements.
	II	G... M... F... C...	With claimed color fastness, comply with CNS 14774 regarding "dye fastness"; "Microbial Index", "Biological Evaluation" or photobiological safety requirements.	
O. 3...	W.. T... W..	–	Walkers without Accessories	Comply with performance specifications such as CNS 15037-1 & ISO 11199-1 or corresponding international standard specifications for "static stability test," "braking effectiveness test," "forward stability test," "rearward stability test," and "sideways stability test," and related performance specification requirements.
		W... w... S...	Comply with performance specifications such as CNS 15037-2 & ISO 11199-2 or corresponding international standard specifications for "forward stability test," "rearward stability test," "sideways stability test," "braking effectiveness test," "upward slope test," and "body usage durability test," performance specification requirements.	
		W... w... S... C...	Comply with performance specifications such as CNS 15037-3 & ISO 11199-3 or corresponding international standard specifications for "forward stability test," "rearward stability test," "sideways stability test," "upward slope test," "body usage durability test," "static strength test," and "upward slope test," performance specification requirements.	

Note: Except as specified above, other performance specifications must also comply with the classification specified in the Medical Device Administration Act when submitted for classification review.

Translated by RegDesk AI

【醫療器材標籤、說明書或包裝得免刊載製造日期及有效期間，或保存期限之規定】

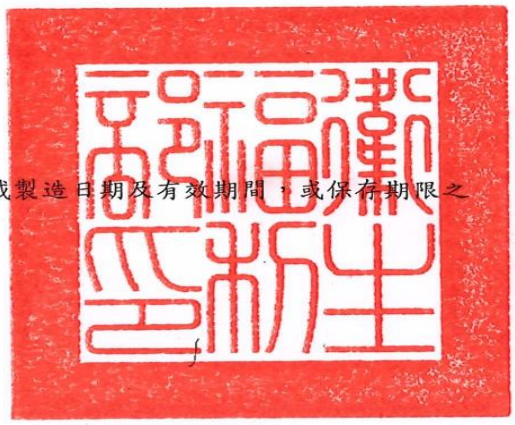
檔　　號：
保存年限：

裝

訂

線

衛生福利部　公告



發文日期：中華民國110年4月28日
發文字號：衛授食字第1101603410號
附件：「醫療器材標籤、說明書或包裝得免刊載製造日期及有效期間，或保存期限之規定」1份

主旨：訂定「醫療器材標籤、說明書或包裝得免刊載製造日期及有效期間，或保存期限之規定」，並自中華民國一百十年五月一日生效。

依據：醫療器材管理法第三十三條第一項。

公告事項：「醫療器材標籤、說明書或包裝得免刊載製造日期及有效期間，或保存期限之規定」如附件。

部長陳時中

第一頁（共一頁）

「Regulations on Exemptions from Manufacturing Dates, Expiry Dates, or Storage Limit Specifications for Medical Device Labels, Instructions, or Packaging」

Ministry of Health and Welfare Announcement

Issued on: April 28, 2021

Document Number: Wei-Shou-Shi-Zi No. 1101603410

Attachment: 1 copy of "Regulations on Exemptions from Manufacturing Dates, Expiry Dates, or Storage Limit Specifications for Medical Device Labels, Instructions, or Packaging"

Explanation:

As per Article 33, Item 1 of the Medical Devices Administration Act.

Announcement:

"Regulations on Exemptions from Manufacturing Dates, Expiry Dates, or Storage Limit Specifications for Medical Device Labels, Instructions, or Packaging" as attached.

Minister of Health and Welfare

Page 1 (Total 1 page)

196

Translated by RegDesk AI

醫療器材標籤、說明書或包裝得免刊載製造日期及有效期間，或保存期限之規定

一、除衛生套、衛生棉塞、乳膠病患檢查手套、滅菌類、植入類及體外診斷試劑之醫療器材外，其餘醫療器材得僅刊載製造日期，免刊載有效期間或保存期限。

二、植入式金屬材質醫療器材，同時符合下列條件者，得僅刊載製造日期，免刊載有效期間或保存期限:

(一)使用前滅菌。

(二)不具分解特性。

(三)非積層製造。

(四)無表面塗覆物質。

三、單獨之軟體類醫療器材(Stand-Alone Software as Medical Device)已標示軟體版本資訊者，得免刊載製造日期及有效期間，或保存期限。

四、使用人力及重力以外能源之醫療器材，其製造日期得僅刊載年、月。

Regulations on Labeling of Medical Device, Instructions or Packaging Indicating Manufacturing Date and Valid Period, or Shelf Life

1. Except for hygiene masks, sanitation materials, breast cancer screening kits, sterilization kits, implant and in vitro diagnostic medical devices, other medical devices must have the manufacturing date labeled, and the valid period or shelf life indicated.

2. Implantable metal material medical devices, which meet all of the following conditions, do not need to have the valid period or shelf life labeled:

(1) Not subject to corrosion before use.

(2) Not biodegradable.

(3) Not manufactured in layers.

(4) Lack of surface coating materials.

3. Stand-Alone Software as Medical Device, with the software version already marked, is exempt from labeling the manufacturing date and valid period, or shelf life.

4. Medical devices that utilize human cells and extracorporeal energy sources, only need to have the manufacturing date labeled, indicating the year and month.

197

Translated by RegDesk AI

【特定醫療器材之標籤、說明書或包裝應加註警語及注意事項】

檔　　號：
保存年限：

裝

訂

線

衛生福利部　公告



發文日期：中華民國110年6月1日
發文字號：衛授食字第1101604586號
附件：「特定醫療器材之標籤、說明書或包裝應加註警語及注意事項」修正附件pdf檔一份

主旨：修正「特定醫療器材之標籤、說明書或包裝應加註警語及注意事項」，並自即日生效。

依據：醫療器材管理法第三十三條第一項第十款。

公告事項：修正「特定醫療器材之標籤、說明書或包裝應加註警語及注意事項」，增列項次13及14之品項及規定如附件。

部長陳時中

第一頁（共一頁）

「Labeling, Instructions, Package Warnings, and Precautions for Designated Medical Devices」

Document No.:

File No.:

Ministry of Health and Welfare Announcement

Issuance Date: June 1, Year 110 of the Republic of China

Document No.: Shu-Yi-Zi No. 1101604586

Attachment: “Labeling, Instructions, Package Warnings, and Precautions for Designated Medical Devices” - one copy

Subject: Amendment of “Labeling, Instructions, Package Warnings, and Precautions for Designated Medical Devices” to be effective immediately.

According to: Article 13, Paragraph 1, Subparagraph 1 of the Medical Device Management Act.

Announcement Details: Amend the “Labeling, Instructions, Package Warnings, and Precautions for Designated Medical Devices” to include the addition of items 13 and 14 as specified in the attachments.

Minister

Chen Shi-Zhong

Page 1 (of 1)

198

Translated by RegDesk AI

特定醫療器材之標籤、說明書或包裝應加註警語及注意事項

項次	特定醫療器材名稱或種類	應加註標示處	應加註之警語及注意事項內容
1	衛生棉條	說明書	一、為避免產生中毒休克症候群(Toxic shock syndrome 簡稱:TSS)的病症，請於月經期間，間隔使用衛生棉條，可選擇白天晚上或某一段時間內使用。 二、曾患過 TSS 者，為防患起見，請先請教醫師，再按指示使用衛生棉條。 三、極少數之婦女在使用衛生棉條時有下列症狀:突發性的發燒(38.9 C 以上)併以嘔吐、腹瀉、手掌及腳掌出現陽光灼傷般之紅疹，使用時如有這些症狀，請即刻取出，趕快就醫。
2	與人體接觸，含天然橡膠製成乳膠之醫療器材	標籤、說明書或包裝	「本產品含有天然橡膠製成之乳膠，可能引起過敏反應。」
3	隱形眼鏡	說明書	「配戴隱形眼鏡操作暨注意事項」(如後附件)。
4	含 Persulfate 成分之假牙清潔劑(清潔錠)	標籤、說明書或包裝	一、本產品含 persulfate 成分，使用後可能造成的過敏反應，包括刺激感、組織傷害、疹子、蕁麻疹、牙齦變軟、呼吸問題、低血壓；如發生任何前述反應時，應將假牙移除並儘快向醫師諮詢。 二、本產品係於容器中使用，切勿放入口中咀嚼、漱口或吞食，並請於使用後將假牙徹底沖洗乾淨。

Designated Medical Device Labeling, Instructions or Package Insert Warnings and Precautions

I... N...	Designated Medical Device Name/Code	Label... Indic...	Warning and Precaution Content
1	Sanitary Pads	Instr...	1. To avoid Toxic Shock Syndrome (abbreviated as TSS): Change pads within a period akin to frequent replacement of sanitary napkins, or use white pads at the start and for a certain period.

2. If experiencing symptoms of TSS, consult a physician before further use.

3. Adolescents should not use sanitary pads during fever. If exhibiting high fever (38.9°C or above) with vomiting, skin rash, or sunburn-like injuries, and if symptoms persist, immediately remove and consult a doctor.

2	**Medical Materials Containing Natural Rubber Latex Associated with Allergies**	**Labeling, Instructions or Packaging**	**"This product contains natural rubber latex which may cause allergic reactions."**

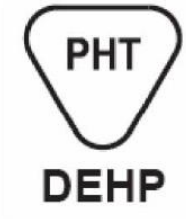
3	**Contact Lenses**	**Instructi...**	**"Read the Contact Lens Operation Precautions" (Refer to attached documentation)**

4	**Denture Cleaners Containing Persulfate (Effervescent Tablets)**	**Labeling, Instruct... or Packaging**	**1. This product contains persulfate ingredients, which may cause allergi reactions such as irritation, allergic reactions, respiratory issues, and low blood pressure; if reactions occur, immediately discontinue use and consult a doctor.**

2. This product is for denture use only; do not place in the mouth or ingest. Rinse dentures thoroughly with warm water after cleaning.

Page 199

Translated by RegDesk AI

5	冷熱凝膠敷包 (Hot/Cold Gel Pack)	標籤、說明書或包裝	一、請勿放置於兒童易取處，並需在成年人監護下使用。 二、如意外誤食產品內之凝膠，應即就近送醫急診，以做評估與進一步處理。
6	可移動式牙科 X 光機	說明書	醫療院所須設有專屬牙科 X 光室且該 X 光機操作時之環境輻射劑量須符合輻防法規標準，倘因部份特殊醫療需要，病人無法至 X 光室內接受檢查，需使用移動型 X 光機於診療床上進行檢查，則醫療院所須另備置移動式鉛屏風，且相關輻射作業亦須同時符合原委會移動型 X 光機輻射安全測試報告之相關規定，以確保就診民眾與工作人員之輻射安全。
7	高 DEHP 暴露風險之 PVC 材質醫療器材[註1]	標籤或包裝	最小販售包裝上應以使用者或消費者可清楚辨識之方式，標示「本產品含有塑化劑 DEHP」或「相關標示符號[註2]，如下圖(兩者擇一)」：  
		說明書	本產品可能溶出塑化劑鄰苯二甲酸二（2- 乙基己基）酯（Di（2-ethylhexyl）phthalate ，DEHP），男嬰、懷孕或授乳婦女、青春期男性等敏感族群使用本產品時，請醫事人員將 DEHP 之健康風險疑慮納入

5. Hot/Cold Gel Pack

Label, Instructions, or Packaging

1. Please store out of children's reach. Pay particular care and use under adult supervision.

2. If the outer packaging is damaged, discontinue use immediately and consult for further action.

6. Portable Dental X-Ray Machine

Instructions

Medical institutions must have exclusive dental X-ray rooms, and portable dental X-ray machines used for rapid filming must comply with radiation protection regulations, ensuring the operator’s safety and staff’s health. If portable dental X-ray machines are used for bedside photography in specific situations, then the medical institution must provide appropriate training and certification for staff involved in the operation of portable dental X-ray machines, in compliance with radiation safety standards to ensure the safety of patients and staff during transport or bedside use.

7. Polymerized Medical Equipment or PVC Material Containing High DEHP Risk

Label or Packaging

When the smallest sales unit uses methods other than conventional sterilization methods, it must include the following indication: "Contains DEHP," as shown below (both options are acceptable):

(Image of labels with text "PHT" and "DEHP")

Instructions

This product may release plasticizer di(2-ethylhexyl) phthalate (DEHP). Pregnant or breastfeeding women, and teenage males using this product should consult medical staff regarding the DEHP-related risks associated with the use of this product.

Translated by RegDesk AI

			臨床治療之考量因素。
8	動力式熱敷墊(Powered heating pad)	標籤、說明書或包裝	一、 禁止使用於嬰兒。 二、禁止使用於癱瘓者及對溫度感覺遲鈍者(例如:孕婦、糖尿病人等)。 三、禁止使用於熟睡者或無意識患者。 四、請勿於易燃環境下、或鄰近充滿氧氣及氧氣儲存設備旁使用。 五、請勿坐或壓在熱敷墊上。 六、請勿以強力壓褶及扭曲方式使用或收納熱敷墊。 七、請勿以拉扯電線方式拔去插頭。 八、請勿以別針或其他金屬物品固定熱敷墊，以避免觸電。
9	未滅菌傳導膠	標籤或包裝	本產品未滅菌，不宜使用於「傷口處」或「應保持無菌的外科手術場合」。
		說明書	本產品未滅菌，使用於「傷口處」或「應保持無菌的外科手術場合」時，有感染風險，臨床使用須符合感染控制之規範。
10	經陰道網膜修補術治療骨盆腔臟器脫垂之手術網片(Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair)	說明書	植入經陰道手術修補網、可能引發網膜糜爛或突出、網膜收縮而引起之陰道縮短、狹窄或疼痛，以及臟器(包括膀胱、腸道、血管)穿孔等併發症。
11	成份為 70-90%酒精者之「一般醫療器械用消毒劑」註 8	標籤、說明書或包裝	一、本產品非藥品。 二、本產品效能僅限於「醫療器材分類分級管理辦法之附表」所列分類分級代碼J.6890 品項鑑別內容「一般用途消毒劑是一種用於不具危險性之醫療器材

Clinical treatment reference considerations

8. Powered heating pad

Label, Instructions, or Packaging

| 1. Do not use on infants.

| 2. Do not use on patients who cannot perceive heat or temperature (e.g., paralyzed, diabetic patients, etc.).

| 3. Do not use on sleeping or unconscious patients.

| 4. Consult operational environment and ensure proper inflation and ventilation to avoid burns.

| 5. Do not fold when in use.

| 6. Operate in correct pressure and curvature.

| 7. Unplug when not in use.

| 8. Do not use other metal objects to secure the heating pad to avoid electric shock.

9. Sterile dressing

Label, Instructions, or Packaging

| This product is sterile; do not use if damaged or packaging is not intact.

Instructions: This product is sterile; if used on wounds or surgical sites with no intact body surface, comply with clinical infection control regulations.

10. Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair

Instructions

| Implantation of surgical mesh in the pelvic cavity may lead to erosion, perforation, pain, sexual difficulties, or organ complications (including bladder, rectum, urethra, blood vessels, nerves, etc.).

11. Contains 70-90% alcohol-based disinfectant such as wipes

Label, Instructions, or Packaging

| 1. This product is non-drug.

| 2. This product is listed as medical disinfectant division under "Guidelines for Classification and Management."

| A. Items listed under code 6890 or specifications not included in general medical device categories.

Translated by RegDesk AI

			及設備表面的殺菌劑，可用於危險或半危險性醫療器材之預洗及去污染處理在最終殺菌或高度消毒之前使用。不具危險性之醫療器材只能與完整的皮膚作局部的接觸」。本產品未核准用於人體殺菌、消毒或手術前消毒。 三、上開內容之標示方式、原則，及不得標示之事項及內容[註4]。
12	玻尿酸皮下植入劑	標籤或包裝	「本產品可能發生罕見但嚴重之副作用，使用前請詳閱中文說明書。」
		說明書	一、玻尿酸植入物誤注入血管可能引起栓塞、血管阻塞、缺血或組織壞死，注射時請格外小心，例如緩慢注射及施加最小所需壓力。玻尿酸植入物曾發生與誤注入血管有關之罕見但嚴重的顏面部副作用，包含暫時或永久視力損傷、失明、腦部缺血、腦部出血、中風、皮膚壞死及顏面內部結構損傷。一旦誤注入血管，病人需及時接受適當醫療處理，也可能需接受合適的醫事人員評估。玻尿酸植入物禁止於全身麻醉下使用。 二、為降低潛在併發症發生風險，玻尿酸植入物建議由受過適當訓練、有經驗及對注射部位解剖學有清楚知識的醫師使用。 三、建議醫師在治療前與病人討論玻尿酸植入物注射的所有潛在風險，並確保病人了解潛在併發症的徵兆及症狀。

12	**Hyaluronic Acid Dermal Filler**	**Packaging or Package Insert**	**"This product may cause serious side effects. Read the statement in detail before using."**

Explanation:

1. Hyaluronic acid injected into blood vessels may cause embolism, ischemia, necrosis of surrounding tissues, permanent blindness, stroke, and in extreme cases, it may cause severe compression of the optic nerve, blindness, and other serious disfigurement injuries, including possible rare facial necrosis and scarring caused by blood vessel embolism or tissue ischemia. It is strictly forbidden for non-medical personnel to inject fillers into the whole body. The injection of hyaluronic acid filler is prohibited for minors under 18 years old.

2. Due to the risk of serious complications from improper injection of hyaluronic acid filler, it is highly recommended for the injector to receive professional medical injection training, fully understand the injection anatomy, and the risks of injections.

3. Physicians should fully communicate with the patients about all the risks of injecting hyaluronic acid fillers and let the patients understand the symptoms and manifestations that may occur.

Translated by RegDesk AI

13	國產平面式醫用口罩（包含一般醫用口罩及外科手術口罩；排除標示或宣稱具N95〔等同或以上〕效果之醫用口罩，及專供外銷用之醫用口罩）	標籤（口罩本體距離邊緣1.5公分內）	以鋼印標示「MD」（即Medical Device縮寫）及「Made In Taiwan」或「Made in Taiwan」字樣，且字高不得小於0.4公分。
14	醫療器材分類分級品項「O.3800 醫療用電動代步器」、「O.3860 動力式輪椅」鑑別品項之產品	車身本體之既有標籤	醫療器材許可證字號。
		標籤、說明書或包裝	產品經核准兼具作為機動車輛中正面向前座椅之特性者，明確標示「本產品已通過機動車輛正面向前座椅之正面衝擊測試」。

註1: 高 DEHP 暴露風險之 PVC 材質醫療器材，係指使用鄰苯二甲酸二（2-乙基己基）酯（Di（2-ethylhexyl）phthalate，DEHP）作為塑化劑之聚氯乙烯（Polyvinylchloride ，PVC） 材質醫療器材，其產品本身或部分用於輸送或移除藥品、體液或其他物質進出人體，或用於運送或儲存

13. Domestic flat medical mask (including general medical masks, medical masks for surgery, masks with removal instructions marked on or above N95, effective masks, winter masks, and masks for use with protective masks)

- Label: (The mask body shall have a label with a minimum font size of 1.5 mm)

- Indicate "MD" (Medical Device abbreviation) and "Made in Taiwan" with copperplate printing. The "Made in Taiwan" must not be smaller than 0.4 cm in font size.

14. Medical equipment classification items "O.3800 Medical Mobile X-ray System", "O.3860 Dynamic Braking Table" and undefined product items

- The main body must have a label

- Medical equipment material must have an identifiable code.

- Labeling: The product manual or packaging

- The product must clearly indicate its function as a vehicle moving within a vehicle's frontal seating area, with explicit labeling "This product has been tested in the interior of a vehicle's frontal seating area."

Note 1: High DEHP risk PVC plastic medical material indicates the use of Di(2-ethylhexyl) phthalate (DEHP) as a plasticizer of polyvinyl chloride (PVC) plastic medical material, which is only used for selective use for air transportation outside of medical service priorities. The intravenous drug category and other goods imported from overseas or domestic production for storage or use for medical reserves.

Translated by RegDesk AI

前開體液或物質者，例如輸液套及延長管路、臍脈導管、血袋及其輸注管路、腸道營養餵食袋、鼻胃餵食管、腹膜透析袋及其管路、用於體外人工血液循環或心肺繞道術之血液管路、血液透析管路等產品。

註 2: PHT 為鄰苯二甲酸酯類(Phthalate)之簡寫。

註 3: 「一般醫療器械用消毒劑」是指「醫療器材分類分級管理辦法之附表」所列分類分級代碼 J.6890 中文名稱。

註 4: 標示方式及原則如下，及不得標示之事項及內容:

(一)「本產品非藥品」字句須以粗黑體字標示，且字體大小不得小於電腦字體 16 號字。

(二)J.6890 鑑別內容應依照衛生福利部公告最新版本「醫療器材分類分級管理辦法之附表」所列內容標示。

(三)不得宣稱或標示非屬 J.6890 鑑別之用途，例如：食具、家具、環境消毒等。

The front page is for liquid objects, such as those used in delivery injection extension tubes, intravenous catheter tubes, blood bags and dialysis equipment, hemoperfusion treatment fibers, tracheal intubation connectors, nasal cannulae, contact lenses and their care solutions. The liquid outside the human body circulates, such as liquid that enters the blood during surgery or transfusion, and regulates body fluid balance items.

Note 2: PHT refers to diethyl phthalate (Phthalate).

Note 3: "General medical equipment or supplies" refers to the names listed in the latest version of the "Medical Materials Classification and Management Codes and Attached Tables" of the Department of Health of the Ministry of Health and Welfare's J.6890 Chinese names.

Note 4: The labeling method and content are as follows. The label must not contain the following items:

(1) Use the product common name or its abbreviation for labeling, and the text height must be no less than 4 mm and no more than 16 mm.

(2) The J.6890 code must be labeled in accordance with the latest version of the "Medical Materials Classification Management Codes and Attached Table" approved by the Department of Health of the Ministry of Health and Welfare.

(3) The classification code J.6890 is marked with the wrong application, such as food, household goods, environmental toxins, etc.

204

Translated by RegDesk AI

配戴隱形眼鏡操作方式暨注意事項

【警告】
隱形眼鏡為直接配戴於眼角膜上之醫療器材，若不遵照鏡片使用方法或不遵守使用上的注意事項，會造成角膜潰瘍、角膜炎(含感染性角膜炎)、角膜浸潤、角膜糜爛、角膜水腫、結膜炎(含巨大乳突性結膜炎)、虹彩炎等傷害。這些傷害中，如果不盡快治療而置之不理，有可能致使眼睛失明。為了安全又正確地使用隱形眼鏡，務必詳閱原製造廠所提供之使用說明書，文字或內容文章有不清楚的地方，務必向眼科醫師詢問，並請妥善保留原製造廠所提供之使用說明書。

壹、軟式隱形眼鏡的處理方式

一、注意事項：

1 初戴者，可從每天戴 4 至 6 小時開始，每日增加 2 小時。
2 若有明顯不適之情形應儘早回診檢查，一切正常則應於一星期後回診。
3 戴上鏡片後再化妝，摘下鏡片後再卸妝。
4 必須知道清潔液、生理食鹽水、保存液、酵素液或酵素片的功用，開瓶後保存期限以說明書內之規定為準。
清潔液-清洗鏡片，生理食鹽水-沖洗鏡片，保存液-浸泡及消毒鏡片，酵素液-去蛋白。
5. 瓶蓋要朝上或側放，不得朝下擺放，以避免污染。
6. 固定先摘戴一眼，再摘戴另一眼(如先右後左)，以免鏡片左右顛倒。
7. 摘鏡片的食指、拇指指甲須剪短，以免摘鏡片時傷到眼球或隱形眼鏡。
8. 戴鏡片時要先分辨鏡片的正(如碗狀)反(如碟狀)面。
9. 所有與隱形眼鏡相關的物品，如鏡片、水盒或藥水等，不得擺放在潮濕處，如浴室。

二、鏡片配戴方法：

1. 用中性肥皂清洗雙手，再擦乾雙手。
2. 將鏡片置於右手食指指腹尖端，正面朝上。
3. 以右手中指拉開下眼皮，左手中指拉開上眼皮。
4. 兩眼直視前方，再將鏡片移至於黑眼珠上。
5. 確認鏡片已戴上，輕轉眼球，再慢慢鬆開雙手。
6. 若鏡片掉落地面或桌面，用姆指及食指抓取其邊緣即可取起。須重新洗乾淨、浸泡、消毒後才可再戴上(確定正反面)。

三、鏡片卸取方法：

1. 眼睛正視前方。
2. 以右手中指拉開下眼皮，左手中指拉開上眼皮。
3. 以右手拇指及食指指腹尖端，輕置於鏡片下緣。
4. 兩指合攏，輕輕取下鏡片。
5. 若鏡片掉落地面或桌面，用姆指及食指抓取其邊緣即可取起。

四、鏡片的清洗及保養方式：

1. 將鏡片放在左手掌心，清潔液搖勻後，倒一或二滴在鏡片上。
2. 以右手食指指腹，將鏡片呈放射狀向外搓揉 20 秒至 30 秒左右。
3. 以生理食鹽水將鏡片沖洗乾淨。
4. 將洗淨的鏡片分別置入水盒中(約七分滿的新鮮保存液)，浸泡 6 小時以上,才可取戴。

五、水盒的保養方式：

1. 每次使用後，揉搓清潔並以隱形眼鏡溶液沖洗乾淨，再用力甩乾後放置陰乾。
2. 建議每三個月換新水盒。

六、酵素片的使用方法：

1. 水盒中注入生理食鹽水，左右各投入一片酵素片，待其完全溶解。
2. 事先以清潔液清洗鏡片，再用生理食鹽水沖淨。
3. 浸泡在酵素溶液中約 30 分鐘（不可超過 2 小時）。
4. 取出鏡片，用清潔液清洗，再用生理食鹽水沖淨。
5. 浸泡在新鮮的保存液中 6 小時以上，才可取戴。

貳、透氧硬式隱形眼鏡的處理方式

一、注意事項：

1. 請依照醫師指示定期回診。
2. 瞭解清潔液、生理食鹽水、保存液及酵素液的功用，並依照說明書內之方法進行清洗及消毒。
3. 瓶蓋要朝上或側放，不得朝下擺放或觸摸瓶口，用完立即蓋妥，以避免細菌污染。(藥水開封後限使用一個月，過期請換新)
4. 所有與隱形眼鏡相關的物品，如鏡片、水盒或藥水，不得擺放在潮濕處，如浴室。
5. 食指、拇指指甲須剪短，以免摘鏡片時傷到眼球或隱形眼鏡。

二、鏡片配戴方法：

1. 用中性肥皂清洗雙手，再用擦手紙將手擦乾。

Instructions and Precautions for Wearing Contact Lenses

[Attention]

Contact lenses are medical equipment prescribed by an optometrist or ophthalmologist. Incorrect wear or handling can cause serious harm to the eye and its vicinity. Adherence to the optometrist's guidance when wearing is essential. Regular follow-ups are necessary. Purchase through an optician authorized by the health department is required. The cleaning and rinsing solutions for contact lenses must be those approved by the health department; characteristics may vary by product. Before using, fully understand the product's usage and validity. If discomfort or abnormal signs occur, suspend use and consult a professional immediately. Contact lenses are part of medical equipment categorized by the Pharmaceutical Affairs Law as "highly controlled medical equipment." Any sales without a license from a qualified optician are prohibited. Document reproduction rights belong to the prescribing optician. Unauthorized copying, reproduction, or reprinting, even partially, is not allowed.

Attached: Key Points for Handling and Usage of Contact Lens Solutions

Instructions and Precautions for Wearing Contact Lenses

1. Precautions

- Follow initial prescription wear time, gradually extend wear time.

- Avoid using expired lenses, lenses in deteriorated condition, or without valid prescription.

- Store in approved cases with the specified solution. Sterile solutions are recommended. Fresh solution each time.

- Replacement of lenses and case should follow recommended schedules.

- Do not use lenses if eyes are irritated or if experiencing discomfort; consult an optometrist.

- Avoid swimming or bathing with lenses on unless waterproof goggles are used.

- Ensure that solutions used for storage and rinsing are fresh; do not use homemade saline or tap water.

2. How to Wear Contact Lenses

- Wash hands thoroughly, dry with a lint-free towel.

- Check the lens for damage before wearing.

- Place lens on fingertip, ensuring the correct side is outward.

- Use other hand to hold eyelid open, place the lens on the eye.

- Blink gently and ensure the lens is comfortable.

3. Removing Contact Lenses

- Wash hands thoroughly, dry with a lint-free towel.

- Look up or aside and gently pinch lens with fingers.

- Place lens in clean case immediately with fresh solution for storage.

6. Lens Care and Storage

- Use only approved solutions for cleaning and soaking lenses.

- Label lens cases to ensure the correct lenses are worn on the correct eyes.

- Replace lens cases every three months.

Translated by RegDesk AI

- Clean and rinse lens cases daily, letting dry in a clean, sterile environment.

Page 1 of 2

205

Translated by RegDesk AI

2. 將鏡片置於右手食指尖端指腹，正面朝上。
3. 以右手中指拉開下眼皮，左手中指拉開上眼皮，將鏡片輕輕放角膜中央。
4. 確認鏡片已戴上，再慢慢鬆開雙手。

三、鏡片卸取方法：

<雙手摘法>

1. 眼睛直視鏡中。
2. 右手中指平按著下眼皮，固定鏡片下緣(勿太用力，以避免眼皮外翻)；左手中指平按著上眼皮，固定鏡片上緣。
3. 眼皮輕眨，鏡片會向下翻落。(注意以手接住)
4. 鏡片掉落地面或桌面上，切勿直接抓取，以免磨損鏡片表面。應該以紙片插入鏡片下面，或加水使鏡片浮起，再行撈起。

<單手摘法>

1. 將下巴稍為縮緊，眼睛張大，正視鏡中。
2. 以食指固定上眼皮，同一手中指固定下眼皮。(若眼睛無法張大，可用食指及中指將上、下眼皮稍微撐開)
3. 兩隻手指往外眼角斜上方拉(要有”緊”的感覺)，此時眼睛持續張大，再往鼻樑的方向看，鏡片會自然的被”推擠”出來。(注意以另一手接住)

<吸棒摘法>

1. 眼睛正視前方。
2. 以左手食指將上眼皮撐開，右手中指將下眼皮拉下。
3. 擠壓吸棒尾端，將吸盤覆上鏡片表面，放鬆擠壓以形成負壓將鏡片吸住。摘出鏡片後，再擠壓吸棒尾端，可除去負壓，取下鏡片。
4. 請務必確定鏡片位置，才可將吸棒吸附上去，以避免吸到眼球。
5. 吸棒摘取鏡片的方式很簡單，但請不要過度依賴它，最好學會徒手摘。

四、鏡片移位的處理方法：

1. 正視前方，眼球不要亂轉。
2. 用手摸眼皮或將眼皮撥開，確定鏡片的位置。(例：右下角)
3. 眼睛先往鏡片相反的方向看。(例：左上角)
4. 手指抵著鏡片外緣(右下角外)，眼睛看回鏡片原先的方向(右下方)。
5. 鏡片回到黑眼球中間，才可摘下鏡片。
6. 若鏡片無法以上述方式移回黑眼珠，待確定位置後可用吸棒吸取。

五、隱形眼鏡水盒的保養方式：

1. 每次使用後，揉搓清潔並以隱形眼鏡溶液沖洗乾淨，再用力甩乾後放置陰乾。
2. 建議每三個月換新水盒。

＊ 另有高溫消毒及双氧水消毒法，以遵照說明書之規定為準。

【禁忌及禁止】

配戴隱形眼鏡者，需依照當下的眼睛或身體的疾病、生活習慣或生活環境的情況，有可能需暫時停止使用隱形眼鏡。請務必經過眼科醫師的診察，確認無礙於疾病及環境後，再使用隱形眼鏡。

禁忌:●前眼部急性或亞急性發炎●眼睛感染●葡萄膜炎●眼瞼異常●角膜知覺低下●角膜上皮缺陷●乾眼及淚管缺陷●過敏●長時間生活在乾燥環境●長時間生活在粉塵、藥品等環境●其他不適合配戴隱形眼鏡者

【注意】

► 隱形眼鏡，請於醒著的時候使用，睡前請摘下。
屬每日拋棄式者，請每天更換新的鏡片(一旦摘下的鏡片，必須拋棄，不要重複配戴)。
其他型式者，請確實遵照原製造廠所提供之使用說明書進行清洗、清潔、保存、拋棄。
► 當配戴中鏡片破損時，請盡快找眼科醫師診治。
► 請不要使用有破損的鏡片。
► 請遵照鏡片更換頻率。
► 請遵照鏡片配戴時間，不要逾時配戴。
隱形眼鏡配戴時間因個人體質而不同，請務必遵照眼科醫師指示。
► 請定期做眼睛檢查。
► 當眼睛感到異常時，請盡快向眼科醫師診治。

【戴隱形眼鏡的危險】

在正確使用隱形眼鏡之下，仍然有可能使角膜內皮細胞減少等生理變化，或因戴隱形眼鏡的關係，鏡片使眼睛氧氣供應量降低，造成角膜上皮受傷或角膜新生血管等眼睛傷害的危險。為不致產生更嚴重的眼科疾病，有任何不適，請及早尋找眼科醫師診治，並定期檢查。

2. Use the thumb and index finger of your left hand to support the rubber surface, align it on top.

3. Alternatively, choose an assembly-type or a kind of rubber sleeve with a simulated leather surface; support the rubber sleeve in the middle with the thumb and index finger of your left hand.

4. Wait until it dries completely; then gently store it back in place.

Handling of cases with few screws:

1. Wait until it is completely dry and gently place it on top.

2. Use the thumb and index finger of your left hand to press down, as you would for a rubber sleeve; then use your right hand to pull it back in a parallel direction and gently install it.

3. After installing, gently press and rotate it once (do not over-tighten).

4. Use adhesive tape for temporary fixation; you may apply a bit of pressure with your right hand on the outside, to guard against accidentally pulling it out from the opposite side. Be careful not to break the adhesive tape on the inside.

Cases with more screws:

1. Place it on top gently, and the positive and negative sides must both be adjustable. Check alignment.

2. Use the thumb and index finger of your right hand to press down (refer to "Method A" in the chapter on weight distribution); press the top edge of the screw with your left index finger, and press the bottom edge with your left thumb to avoid the entire device from being tilted. Wait until the bottom edge of the screw is fixed on the surface.

3. In step 2, avoid exerting force upwards or backwards, as force from a perpendicular direction can cause the adhesive joint to break or get stuck at the critical seam and not be pulled onto the cover surface. Gently press from the back so the glue does not break.

4. After it dries, tighten slightly; too much tightness is unnecessary. The cover stays smooth and attractive and does not make noise when spinning.

Handling of larger unauthorized installations:

1. Gently adjust the alignment.

2. Use the thumb and index finger of your right hand to press down, while your left hand holds the raised part down.

3. Remove wrappers and rub down manually, but greatly reinforce the stability of the wrapped foil and the marginal effect. It is common for some parchment to remain because the tape cannot be thoroughly pressed into the equipment.

4. Cut or remove parts that are too long.

5. Attach necessary small fasteners; cut with scissors in areas that are too long, or check for reinforcement.

6. Apply A adhesive in the ways mentioned, but keep its body in place or take it apart if problem insertion ensues.

Regarding assembly explanation:

1. Using commercially available methods:

2. Adjust to level; don't break, rotate, or damage it; fix to the chassis in the correct direction; once the correct alignment is achieved, slide from the lifting handle with caution to create a firmish support and avoid deformation. Gently and thoroughly tighten the nut and pressurize with care.

Translated by RegDesk AI

Reminder: Please refer to the assembly instructions on pages **-* for detailed instructions.

【Tightening Instructions】

Due to the side force problem, your elbow is automatically applied using a tightened knob after drying. It's necessary to exert pressure and turn counter-clockwise.

● Please ensure that you purchase screws that fit closely according to your schemes, unless you install measurement screws.

● Eventually, when using a rotating slanted fastener, tick only the screws lower than the rotating point, avoid briefly applying pressure counter-directionally. You should use special rubberized sticky sleeves.

● You can use all mentioned assembly aid materials, but restricted around an installation window.

【Caution】

For installation procedures, please bear in mind:

● If any problems occur, use the requisite installation tools;

● When purchasing suits, ensure that spare parts must be purchased and carried as part of your repaired device; necessarily replace any that couldn't be accurately fixed.

● Do not overbind when replacing the part, to avoid excessive cohesion for specifically described products.

● The installation of devices in excess of 1 mm is entirely unnecessary.

● The weight distribution in the manual cannot be altered; please follow recommended installation tips.

Instructions for Assembly of Problematic Devices

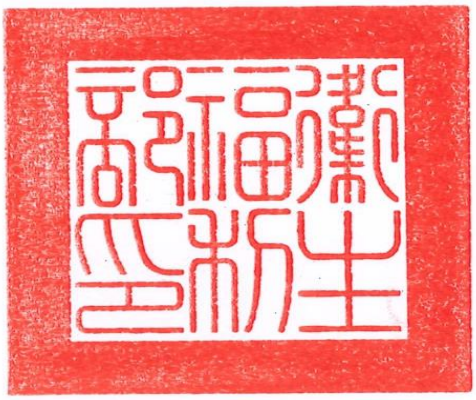
Through reasonable repairs, the components may still experience repeated removal and installation issues. Under the situation of non-essential repairs, you may align downwardly through included but additional slight modifications—other separately designed specific creatures must be lengthened or checked. Steps for regular maintenance are for extended components "if necessary" assembled accordingly. Stepwise to life habits can be implemented to counter the regular equipment use and not for irregular models and/or ** учащ.

Translated by RegDesk AI

【依醫療器材管理法第二十五條第四項規定，由中央主管機關逕予登錄及註銷原許可證者，產品標籤、說明書或包裝相關規定】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年8月5日
發文字號：衛授食字第1101607343號
附件：

裝

主旨：訂定「依醫療器材管理法第二十五條第四項規定，由中央主管機關逕予登錄及註銷原許可證者，產品標籤、說明書或包裝相關規定」，並自即日生效。

訂

依據：醫療器材管理法第三十三條第一項。

公告事項：依醫療器材管理法第二十五條第四項規定，由中央主管機關逕予登錄及註銷原許可證者，自中央主管機關逕予登錄日起算二年內製造之產品，其產品標籤、說明書或包裝有標示原許可證字號者，得免標示登錄字號。

線

部長 陳時中

第一頁（共一頁）

According to the provisions of Article 25, Item 4 of the Medical Device Management Act, the central competent authority may choose to exempt from registration and certification by the original manufacturer, product labeling, instructions, or packaging

Ministry of Health and Welfare Announcement

Document Date: August 5, 2021

Document Number: Wei-Shu-Yi-Zi No. 1101607343

Attachments:

Subject: "According to Article 25, Item 4 of the Medical Device Management Act, the central competent authority may choose to exempt from registration and certification by the original manufacturer, product labeling, instructions, or packaging," effective immediately.

According to: Article 13, Item 1 of the Medical Device Management Act.

Announcement Item: According to the provisions of Article 25, Item 4 of the Medical Device Management Act, the central competent authority may choose to exempt from registration and certification by the original manufacturer. If the central competent authority chooses to exempt, the product shall be marked with the original manufacturer's certification number on the labeling, instructions, or packaging, and may be exempted from indicating the registration number.

Minister of Health and Welfare

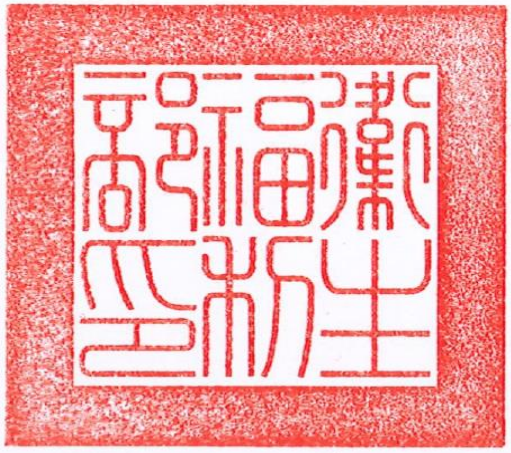
Page 1 (Total 1 Page)

Translated by RegDesk AI

【醫療器材標籤應刊載單一識別碼規定】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國112年2月13日
發文字號：衛授食字第1121600286號
附件：醫療器材標籤應刊載單一識別碼規定

裝

主旨：訂定「醫療器材標籤應刊載單一識別碼規定」，並自即日生效。

訂

依據：醫療器材管理法第33條第1項第10款。

公告事項：

一、訂定「醫療器材標籤應刊載單一識別碼規定」(如附件)。

二、本部110年4月6日衛授食字第1101602479號公告之「醫療器材標籤應刊載單一識別碼規定」，自即日廢止。

線

部長 薛瑞元

□Regulations on Barcode Labeling for Medical Devices□

Publication Date: February 13, 2023

Document Number: Shu-Chih-Hsiao-Tzu 1121600286

Attachment: Regulations on Barcode Labeling for Medical Devices

Ministry of Health and Welfare Announcement

Seal (red stamp)

According to: Article 33, Paragraph 1, Subparagraph 10 of the Medical Devices Management Act.

Announcement Details:

1. The "Regulations on Barcode Labeling for Medical Devices" have been amended and are effective immediately as per the attachment.

2. The previous "Regulations on Barcode Labeling for Medical Devices" announced on April 6, 2021, under Document Number 1101602479, are hereby abolished.

Minister

(signature)

Page 1 of 1

208

Translated by RegDesk AI

醫療器材標籤應刊載單一識別碼規定

一、本規定依醫療器材管理法第三十三條第一項第十款規定訂定之。

二、第二等級及第三等級醫療器材之單一包裝或器材本體上，應標示單一識別碼（Unique Device Identifier, UDI）；如單一包裝或器材體積過小，應標示於最小販售包裝上。

三、前點醫療器材符合下列條件之一者，免予標示 UDI：

(一)客製化醫療器材。

(二)外銷專用醫療器材。

(三)醫療器材組合包及體外診斷醫療器材內，僅供單次使用，且非單獨使用及販售之非植入式醫療器材組件。

四、醫療器材許可證所有人或登錄者，應將單一識別碼之產品對應資訊，登載至衛生福利部建置之醫療器材單一識別系統資訊管理平臺（UDI Database, UDID）；識別碼之編碼、標示及產品對應資訊之登載，規定如附件一；產品對應資訊登載內容，規定如附件二。

五、不同風險等級醫療器材適用期程如下：

(一)自中華民國一百十年六月一日起製造之國產及輸入第三等級植入式醫療器材。

(二)自中華民國一百十一年六月一日起製造之國產及輸入第三等級非植入式醫療器材。

(三)自中華民國一百十二年六月一日起製造之國產及輸入第二等級醫療器材。

六、附件三所列之第二等級醫療器材分類分級品項，其單一識別碼得免標示生產識別碼(PI)。

Regulations on the Application of Unique Device Identifiers on Medical Device Labels

1. These regulations are specified in accordance with Paragraph 1, Article 33 of the Medical Device Management Act.

2. For packaging of second-level and third-level medical devices, the body of the package should display a Unique Device Identifier (UDI). If the single package or material is too small, the identifier should be displayed on the smallest sales unit package.

3. Exemption from displaying a UDI is granted if any of the following conditions apply:

(1) Custom-made medical devices.

(2) Medical devices for dental use.

(3) Medical device sets and diagnostic medical devices intended for professional use only, and not for sale as non-implantable individual medical device components.

4. Any party that links traceable information with the identifiable information through identification codes should provide such information, register it with the UDI Database, and follow compliance conditions in accordance with the registration requirements. When products are on the market, additional stipulations provided in Appendix 2 should be adhered to.

5. Implementation timelines for medical devices of varying risk levels are as follows:

(1) From January 1, 2021, imported or domestically manufactured second and third-level non-implantable medical devices.

(2) From January 1, 2022, imported or domestically manufactured third-level non-implantable medical devices.

(3) From January 1, 2023, imported or domestically manufactured second-level medical devices.

6. The subcategories of products in Appendix 2 for second and third-level medical devices that are divided into various grades are exempt from displaying the production identification code (PI).

Translated by RegDesk AI

附件一　醫療器材單一識別碼之編碼、標示及其產品對應資訊之登載

一、本規定用詞，定義如下：

(一) 醫療器材單一識別碼(Unique Device Identifier，UDI)：

依發碼組織訂定之編碼標準，針對單一特定型號規格之醫療器材，給予一串數字或文字與數字，作為識別。

(二) 產品識別碼 (Device Identifier，DI)：

為識別特定醫療器材類別(如製造廠、型號、版本等)之編碼。

(三) 生產識別碼(Production Identifier，PI)：

為識別醫療器材生產資訊(如批號、序號、製造日期、保存期限等)之編碼。

(四) 醫療器材單一識別系統資訊管理平台(Unique Device Identification Database，UDID)：

由衛生福利部建立及維護之醫療器材單一識別系統資訊管理平臺。

(五) 人眼可識別標示 (Human Readable Interpretation，HRI)：

在UDI 標示中，以數字或文字與數字呈現，由人眼即可解讀。

(六) 機器可識別標示(Automatic identification and data capture，AIDC)：

在UDI標示中，應透過自動化流程取得產品識別資訊之標示方式。

(七) 植入式醫療器材（Implantable Device）：

醫療器材之本體全部或部分依下列方式使用，持續留置三十日以上，並藉由外科或其他醫療方式取出之器材：

1. 經手術或其他方式植入人體。
2. 直接置放於人體自然腔道內。
3. 直接置放並替代上表皮或眼表面。

二、醫療器材單一識別之編碼及標示，規定如下：

(一) 醫療器材製造廠應完成產品單一識別碼之編碼及標示。

(二) 編碼原則如下：

1. 依國際醫療器材法規論壇（International Medical Device Regulators

Appendix 1 Unique Device Identification Codes, Marking, and Product Information Upload Guidelines

I. Definitions:

(1) Unique Device Identifier (UDI):

A series of numeric or alphanumeric characters defined by a manufacturer's code, providing identification for the specific model of a medical device.

(2) Device Identifier (DI):

The code that identifies the specific version or model of a device (e.g., manufacturer, model, version, etc.).

(3) Production Identifier (PI):

The code identifying device production information (e.g., lot number, serial number, manufacturing date, expiration date, etc.).

(4) Unique Device Identification Database (UDID):

The platform established to compile and maintain the unique device identification information.

(5) Human Readable Interpretation (HRI):

Numbers or characters within the UDI marking that can be read by humans.

(6) Automatic identification and data capture (AIDC):

Technology to obtain identification data in the UDI marking through automated procedures.

(7) Implantable Device:

A device entirely or partly implanted in the human body or used by surgical means for more than 30 days and can only be removed through medical or surgical procedures, including:

1. Procedures involving insertion of the device into the body through surgery.

2. Naturally orificed body cavities for device placement.

3. Placement on body surfaces or in the mouth.

II. Unique Device Identification Codes, Marking Rules:

(1) Devices should be marked with a Unique Device Identification Code.

(2) Coding principles:

1. According to the International Medical Device Regulators Forum guidelines.

Translated by RegDesk AI

Forum，IMDRF）建議之編碼組織訂定之標準進行產品編碼，應包括DI及 PI。

2. DI 應具有全球唯一性，代表特定醫療器材產品型號規格。

3. 醫療器材變更為新型號(版本)或新包裝，DI 應更新。

(三) 標示原則如下：

1. 應包括HRI及AIDC之形式。

2. UDI標示不得改變或影響原有醫療器材標示。

3. AIDC應使用符合國際標準之一維條碼、二維條碼或無線射頻識別（Radio Frequency Identification, RFID）電子標籤。

4. 核定為可重複使用之醫療器材，在產品生命週期內，UDI標示應清晰可識別。

5. 醫療器材組合包及體外診斷醫療器材內之組件，為可重複使用醫療器材，或可單獨販售者，其各別組件應具有UDI標示。

6. 醫療器材軟體之PI，應為醫療器材軟體版本；其不經實體販賣流通者，應在啟動畫面或軟體資訊頁呈現HRI，無需具有AIDC。

三、醫療器材單一識別產品對應資訊之登載，規定如下：

(一)醫療器材許可證所有人或登錄者，應於產品市面流通前，至UDID平臺登載DI及對應資料；應登載之資訊欄位，不得空白。

(二)DI有變更者，醫療器材許可證所有人或登錄者，應於產品市面流通前，將變更之DI及對應資訊，至UDID平臺登載。

Forum, IMDRF's recommended coding structure for the standardization of product labeling should include DI and PI.

1. DI should have uniqueness, representing the specified medical device's model specifications.

2. If the medical device is double-packed as a new model (version) or repackaged, the DI should update.

3. The labeling principles are as follows:

(1) Should include HRI and AIDC formats.

(2) The UDI label must not replace or affect the original medical device label.

(3) AIDC should be carried on a two-dimensional barcode or radio frequency identification (RFID) electronic tag in line with international standards.

(4) Labels on reusable medical devices that may be sterilized should be legible during usage.

(5) For medical device kits containing both equipment and diagnostic devices as components, to ensure reusability, the components should have their own UDI labels if they are independently used and those separately sold should have UDI labels.

(6) Medical device software is considered a new version if it is modified; it should automatically update the label information or demonstrate HRI, even if no AIDC is available.

3. The medical device identification rules for applying for product registration are as follows:

(1) The device license holder or all registrants should apply to the UDID platform before the product enters the market to record DI and corresponding data, with no empty fields.

(2) If there are changes to DI, the device license holder or all registrants should apply to the UDID platform prior to the product market entry to update DI and corresponding data.

Translated by RegDesk AI

附件二　UDID平臺產品對應資訊登載內容

一、許可證字號(License No)。
二、許可證字號(類型)(License Type)。
三、UDI 發碼機構(Issuing Agency)。
四、基本 DI(Primary DI Number)。
五、型號(Catalog Number)。
六、產品描述(Device description)。
七、廠商聯絡電話(Phone)。
八、廠商電子郵件(Email)。
九、是否為單次使用器材(For Single-Use)。
十、是否可重覆使用器材(For Multiple-Use)。
十一、產品標示是否有批號(Lot or Batch Number)。
十二、產品標示是否有製造日期(Manufacturing Date)。
十三、產品標示是否有序號(Serial Number)。
十四、產品標示是否有置架期(保存期限)(Expiration Date)。
十五、產品標示是否含有天然橡膠(乳膠)成份(Device required to be labeled as containing natural rubber latex or dry natural rubber)。
十六、產品標示是否含有 DEHP(塑化劑)成分(Device required to be labeled as containing DEHP)。
十七、產品標示尺寸類型(Size Type)。
十八、產品標示尺寸大小(Size)。
十九、產品標示尺寸單位(Size Type Unit)。
二十、產品標示之其他尺寸單位(Other Size Type)。
二十一、器材儲存/使用環境要求類別(Storage and Handling)。
二十二、器材儲存/使用環境要求之下限(Low value)。
二十三、器材儲存/使用環境要求之上限(High value)。
二十四、器材儲存/使用環境要求之單位(Unit of Measure)。

Appendix 2 Content of UDID Platform Product Information Upload

1. License No.
2. License Type
3. Issuing Agency of UDI
4. Primary DI Number
5. Catalog Number
6. Device description
7. Manufacturer contact phone
8. Manufacturer email
9. For Single-Use
10. For Multiple-Use
11. Lot or Batch Number
12. Manufacturing Date
13. Serial Number
14. Expiration Date
15. Device required to be labeled as containing natural rubber latex or dry natural rubber
16. Device required to be labeled as containing DEHP
17. Size Type
18. Size
19. Size Type Unit
20. Other Size Type
21. Storage and Handling
22. Low value of storage/environment requirements
23. High value of storage/environment requirements
24. Unit of Measure for storage/environment requirements

Translated by RegDesk AI

附件三 第二等級醫療器材得免標示生產識別碼（PI）之分類分級品項

項次	分類分級代碼	中文品項名稱	英文品項名稱
1	E.1120	血壓壓脈帶	Blood pressure cuff
2	E.2770	醫療用阻抗式體積描記器(阻抗式週邊血流描記器)	Medical Impedance plethysmograph
3	G.5220	耳鼻喉佈施藥裝置及其搭配使用之物質	Ear, nose, and throat drug administration device
4	I.0004	酒精棉片	Alcohol pad
5	I.0005	優碘棉片	Providone-Iodine pad
6	I.4014	外部使用非吸收式紗布或海綿球	Nonresorbable gauze/sponge for external use
7	I.4040	醫療用衣物	Medical apparel
8	J.0001	沖洗用之生理食鹽水	Saline solution for wound irrigation
9	J.2910	臨床電子體溫計	Clinical electronic thermometer
10	J.5240	醫療用黏性膠帶及黏性繃帶	Medical adhesive tape and adhesive bandage
11	J.5780	醫用輔助襪	Medical support stocking
12	L.5300	衛生套(保險套)	Condom
13	L.5310	含殺精劑的衛生套	Condom with spermicidal lubricant
14	L.5400	月經量杯	Menstrual cup
15	L.5460	具香味或除臭的衛生棉塞	Scented or scented deodorized menstrual tampon
16	L.5470	無香味的衛生棉塞	Unscented menstrual tampon
17	M.5925	軟式隱形眼鏡	Soft (hydrophilic) contact lens
18	M.5916	硬式透氣隱形眼鏡	Rigid gas permeable contact lens
19	M.5918	硬式透氣隱形眼鏡保存用產品	Rigid gas permeable contact lens care products
20	M.5928	軟式隱形眼鏡保存用產品	Soft (hydrophilic) contact lens care products
21	O.3800	醫療用電動代步器	Motorized vehicle for medical purposes
22	O.3860	動力式輪椅	Powered wheelchair

Appendix III

List of production identification codes (PI) exempt from labeling for secondary medical devices and equipment classification codes

Item No.	Classification Code	Chinese Product Name	English Product Name
1	E.1120	□□□□□	Blood pressure cuff
2	E.2770	□□□□□□□□□□□ (□□□□□□□□□□□)	Medical Impedance plethysmograph
3	G.5220	□□□□□□□□□□□□□□□□□	Ear, nose, and throat drug administration device
4	I.0004	□□□□	Alcohol pad
5	I.0005	□□□□	Providone-Iodine pad
6	I.4014	□□□□□□□□□□□□□□□	Nonresorbable gauze/sponge for external use
7	I.4040	□□□□□	Medical apparel
8	J.0001	□□□□□□□□□	Saline solution for wound irrigation
9	J.2910	□□□□□□□	Clinical electronic thermometer
10	J.5240	□□□□□□□□□□	Medical adhesive tape and adhesive bandage
11	J.5780	□□□□□	Medical support stocking
12	L.5300	□□□ (□□□)	Condom
13	L.5310	□□□□□□□□	Condom with spermicidal lubricant
14	L.5400	□□□□	Menstrual cup
15	L.5460	□□□□□□□□□□□	Scented or scented deodorized menstrual tampon
16	L.5470	□□□□□□□□	Unscented menstrual tampon
17	M.5925	□□□□□□	Soft (hydrophilic) contact lens
18	M.5916	□□□□□□□□	Rigid gas permeable contact lens
19	M.5918	□□□□□□□□□□□□	Rigid gas permeable contact lens care products
20	M.5928	□□□□□□□□□□	Soft (hydrophilic) contact lens care products
21	O.3800	□□□□□□□□	Motorized vehicle for medical purposes
22	O.3860	□□□□□	Powered wheelchair

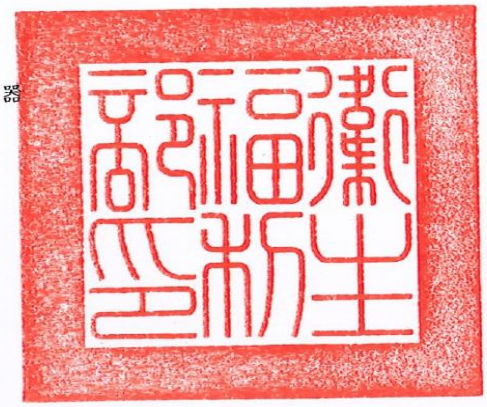
Translated by RegDesk AI

【得以電子化說明書取代中文說明書之醫療器材品項及其標籤或包裝應加註事項】

檔　　號：
保存年限：

衛生福利部　公告

發文日期：中華民國112年3月29日
發文字號：衛授食字第1121601600號
附件：得以電子化說明書取代中文說明書之醫療器材品項及其標籤或包裝應加註事項



裝

主旨：訂定「得以電子化說明書取代中文說明書之醫療器材品項及其標籤或包裝應加註事項」，並自即日生效。

訂

依據：醫療器材管理法第三十三條第一項第十款及第二項。

公告事項：訂定「得以電子化說明書取代中文說明書之醫療器材品項及其標籤或包裝應加註事項」（如附件）。

部長 薛瑞元

線

第1頁　共1頁

「Notes on Replacing Chinese Instructions with Electronic Instructions for Medical Devices and Their Markings or Packaging」

Ministry of Health and Welfare Announcement

Document No.: Taiwan Proclamation No. 11216010600

Date: March 29, 2023

Subject: Approval of "Notes on Replacing Chinese Instructions with Electronic Instructions for Medical Devices and Their Markings or Packaging," effective immediately.

According to: Article 33, Paragraph 1, Subparagraph 10, Item 2 of the Medical Device Management Act.

Announcement details: Approval of "Notes on Replacing Chinese Instructions with Electronic Instructions for Medical Devices and Their Markings or Packaging" (see attachment).

Minister

[SIGNATURE]

Page 1 of 1

214

Translated by RegDesk AI

得以電子化說明書取代中文說明書之醫療器材品項及其標籤或包裝應加註事項

一、電子化說明書，指以下列方式之一提供說明書：

(一)內建於醫療器材（如：Help 系統）。

(二)由醫療器材商或製造業者提供之可攜式電子儲存裝置(如：光碟、隨身碟）。

(三)由醫療器材商或製造業者之網站取得。

二、得以電子化說明書取代中文說明書之醫療器材品項：

(一)須由醫事人員使用之醫療器材。

(二)經由通訊交易通路販售之醫療器材軟體。

三、以電子化說明書取代中文說明書之醫療器材，其標籤或包裝除依醫療器材管理法第三十三條第一項及同法施行細則第十九條規定刊載外，應加註：

(一)「本產品提供電子化說明書，如需紙本說明書，請與醫療器材商聯繫」之文字。

(二)醫療器材商聯繫資訊（如：電話、電郵）。

(三)經由網路取得電子化說明書者，應刊載其連結路徑(如：網址、QR code）。

Matters for Using Electronic Instructions to Replace Chinese Instructions for Medical Device Items and Their Labeling or Packaging

1. Electronic instructions refer to providing instructions in one of the following ways:

(1) Built-in medical equipment (e.g., Help system).

(2) Provided by the medical device supplier or manufacturer on electronic storage devices (e.g., CD, USB).

(3) Obtained from the website of the medical device supplier or manufacturer.

2. Conditions for using electronic instructions to replace Chinese instructions for medical device items:

(1) Must be used by professional healthcare personnel.

(2) Must be medical device software that is traded and distributed via electronic means.

3. When using electronic instructions to replace Chinese instructions for medical devices, their labeling or packaging, apart from following the provisions of Article 33, Paragraph 1, Item 2 of the Medical Device Management Regulations, should include:

(1) Words indicating "This product provides electronic instructions" and "Please contact the medical device supplier for the written instructions."

(2) Contact information of the medical device supplier (e.g., phone, email).

(3) When electronic instructions are accessed via the internet, the link path should be included (e.g., web address, QR code).

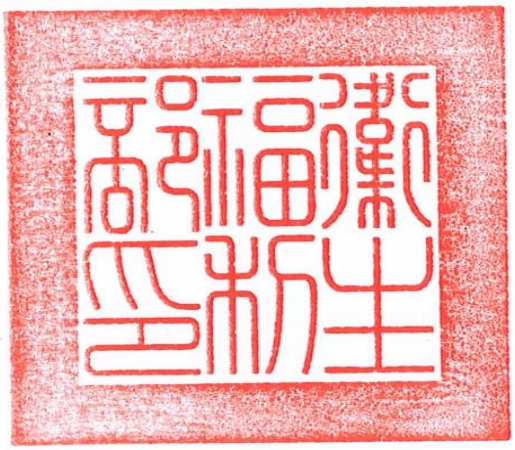
215

Translated by RegDesk AI

【無顯著風險之醫療器材臨床試驗態樣】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年4月27日
發文字號：衛授食字第1101603684號
附件：

裝

主旨：訂定「無顯著風險之醫療器材臨床試驗態樣」，並自中華民國一百十年五月一日生效。

訂

依據：醫療器材管理法第三十七條第一項但書。

公告事項：

一、臨床試驗機構或試驗委託者發起醫療器材臨床試驗，應申請中央主管機關核准後，始得為之。醫療器材臨床試驗符合下列條件之一者，屬無顯著風險之醫療器材臨床試驗，免予申請中央主管機關之核准：

(一)試驗用醫療器材已依醫療器材管理法規定取得許可證或登錄，且其臨床試驗之預期用途、使用方式及技術特點均未超出核准範圍；其登錄者，未超出鑑別範圍。

線

(二)試驗用醫療器材，逕以合法取得之受試者檢體或資料作為診斷試驗之客體，且其試驗階段所得之結果不作為臨床診斷之依據。

(三)未具游離輻射之試驗用醫療器材，其使用係置於受試

□Low-Risk Medical Device Clinical Trial Model□

Ministry of Health and Welfare Announcement

Issuance Date: April 27, 2021 (ROC Year 110)

Document Number: Shu-Shou-Chi No. 1101603684

Attachment: None

Subject: Determination of "Low-Risk Medical Device Clinical Trial Model," effective from May 1, 2021.

Basis: Article 37, Paragraph 1 of the Medical Device Management Act.

Announcement Details:

1. When clinical trial institutions or trial sponsors plan to conduct medical device clinical trials, applications must be approved by the main regulatory agency. If they meet any of the following conditions, they are classified as low-risk medical device trials and are exempt from submitting applications to the main regulatory agency for two reviews:

(1) The medical device in the trial has already obtained approval registration under the Medical Device Management Act. The clinical trial is within the scope of approved purposes, indications, methods, or technical specifications, and does not exceed the approved range; if it exceeds, it does not exceed the range specified in:

a. Labels: does not exceed label specifications.

(2) The medical device in the trial has not obtained legal approval to collect from a subject or data and serve as a reference for trial results, and trial results shall not serve as a basis for clinical diagnosis.

(3) The trial does not involve investigative use of radiation-emitting medical devices; if used, they are placed outside the trial.

Page 1 (Total 2 pages)

216

Translated by RegDesk AI

者之體表或無須與受試者體表接觸，進行資料收集試驗，或就其所收集之資料為診斷試驗，且其試驗階段所得之結果不作為臨床診斷之依據。

二、前點之資料，指受試者之檢驗數據、醫學影像、生理參數或病歷。

部長陳時中

The subject who needs to undergo a medical examination form and the subject who undergoes a medical examination form need to undergo data collection form completion, or undergo the data collection form completion test of the subject's affiliated unit as a reference diagnostic examination. However, the results of this examination phase shall not be used as a basis for clinical diagnosis.

II. The aforementioned data refers to the laboratory data, medical images, physiological parameters, or medical records of the examinee.

Minister

Chun-Shih Chen

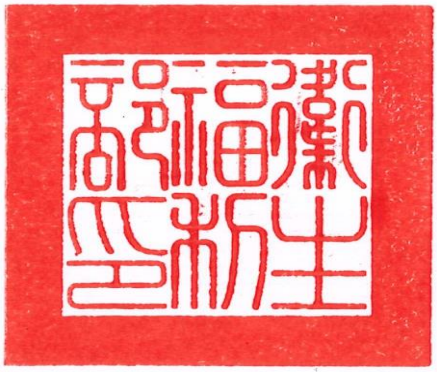
217

Translated by RegDesk AI

【除日戴型每日拋棄式隱形眼鏡外，其餘隱形眼鏡之廣告，以登載於專供醫事人員閱聽之醫療刊物、傳播工具，或專供醫事人員參與之醫療學術性相關活動為限】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年4月22日
發文字號：衛授食字第1101602936號
附件：

裝

主旨：公告訂定「除『日戴型每日拋棄式隱形眼鏡』外，其餘隱形眼鏡之廣告，以登載於專供醫事人員閱聽之醫療刊物、傳播工具，或專供醫事人員參與之醫療學術性相關活動為限」，並自中華民國一百十年五月一日生效。

訂

依據：醫療器材管理法第四十四條。

公告事項：除「日戴型每日拋棄式隱形眼鏡」廣告，不限刊登途徑外，其餘隱形眼鏡之廣告以登載於專供醫事人員閱聽之醫療刊物、傳播工具，或專供醫事人員參與之醫療學術性相關活動為限。

線

部長陳時中

第一頁（共一頁）

Except for advertisements of daily-wear disposable contact lenses, other contact lens advertisements are limited to medical publications, transmission tools for medical professionals, or medical academic activities related to medical professionals

Ministry of Health and Welfare Announcement

Document Date: April 22, 2021, Republic of China

With the authorization of the Ministry of Health No. 1101602936

Subject: Announcing the provision that "Except for advertisements of daily-wear disposable contact lenses, other contact lens advertisements are limited to medical publications, transmission tools for medical professionals, or medical academic activities related to medical professionals" will be effective from May 1, Republic of China.

Basis: According to the regulations of the Scope of Business Operation Permits for Medical Devices.

Announcement Item: Except for advertisements of daily-wear disposable contact lenses, other contact lens advertisements shall not be published, except as required for the use in medical publications, transmission tools for medical professionals, or medical academic activities related to medical professionals.

Minister: Chen Shizhong

Page 1 (Page 1 of 1)

Translated by RegDesk AI

【應執行安全監視之醫療器材品項】

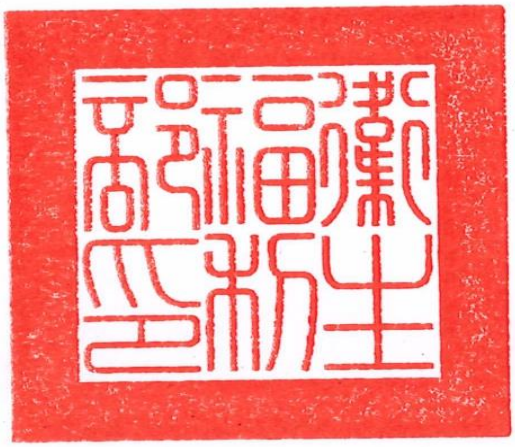
檔　　號：
保存年限：

裝

訂

線

衛生福利部　公告



發文日期：中華民國110年4月28日
發文字號：衛授食字第1101603223號
附件：「應執行安全監視之醫療器材品項」

主旨：訂定「應執行安全監視之醫療器材品項」，並自中華民國一百十年五月一日生效。

依據：醫療器材管理法第四十七條第一項及第三項。

公告事項：訂定「應執行安全監視之醫療器材品項」（如附件）。

部長陳時中

第一頁（共一頁）

□Items for Implementing Safety Monitoring of Medical Devices□

Ministry of Health and Welfare Announcement

Issue Date: April 28, 2021

Document Number: Ministry Order No. 1101603223

Attachment: "Items for Implementing Safety Monitoring of Medical Devices"

Main Content: The "Items for Implementing Safety Monitoring of Medical Devices" is enacted, effective from May 1, 2021.

According to: Article 47, Paragraph 1 and Paragraph 3 of the Medical Device Management Act.

Announcement: Enactment of "Items for Implementing Safety Monitoring of Medical Devices" (as attached).

Minister: Chen Shih-chung

Page 1 (of 1)

219

Translated by RegDesk AI

應執行安全監視之醫療器材品項

一、 本規定依醫療器材管理法第四十七條第一項及第三項規定訂定之。

二、 應執行安全監視之醫療器材品項如下，監視期間自發證日起三年：

（一） 塗藥血管支架（Drug-Eluting Stents, DES)。

（二） 第一個核准上市國為我國之第三等級醫療器材。

（三） 經陰道骨盆腔器官脫垂治療用手術網片（Surgical mesh for transvaginal pelvic organ prolapse repair，簡稱經陰道手術修補網)：本器材為由合成、非合成、或混合合成與非合成的多孔隙植入物，用以加強骨盆底部之軟組織強度。

三、 前點醫療器材執行安全監視之方式，依醫療器材安全監視管理辦法第三條第一款之規定辦理。

四、 醫療器材許可證所有人執行醫療器材安全監視前，應訂定安全監視計畫書，其應載明之項目、內容及格式，規定如下：

（一） 項目：依醫療器材安全監視管理辦法第五條第三項之規定辦理。

（二） 內容及格式：如附件一至附件三。

五、 本規定生效前，第二點醫療器材已執行安全監視，而監視期尚未屆滿者，應依醫療器材安全監視管理辦法之規定，完成後續安全監視作業。

List of Medical Devices Subject to Safety Surveillance

I. This regulation is enacted pursuant to Paragraph 1, Article 47 and Subparagraph 2, Article 65 of the Medical Devices Management Act.

II. The following medical devices are subject to safety surveillance for a period of three years from the date of release:

(1) Drug-Eluting Stents, DES.

(2) New devices approved for listing for the first time as Class III medical devices.

(3) Surgical mesh for transvaginal pelvic organ prolapse repair: Composed of synthetic or non-synthetic material, absorbable or non-absorbable, with or without additional materials like pore-forming substances, used to reinforce the vaginal wall.

III. Before the medical devices listed in the preceding paragraph are subjected to safety surveillance, the management shall be handled in accordance with Article 3 of the Medical Devices Management Act's general rules.

IV. Before any medical device is subjected to safety surveillance, it must submit a safety surveillance plan for review. The content and format are specified below:

(1) Item: Managed pursuant to Subparagraph 2, Article 65 of the Medical Devices Management Act.

(2) Content and format: Refer to Appendix 1 to Appendix 3.

V. Before the enforcement of this regulation, medical devices listed in Subparagraph 2 are subjected to safety surveillance. If the surveillance period is not complete, follow the procedures of the Medical Devices Management Act to complete the safety surveillance process.

220

Translated by RegDesk AI

附件一

塗藥血管支架（Drug-Eluting Stents, DES）

（請以正體中文依格式填寫及詳述說明，不可自行刪減項目或僅寫「詳見附件」。
檢附之附件資料如非正體中文或英文者，應另附正體中文或英文譯本。）

一、醫療器材產品資料

（一）許可證字號：

（二）中文品名：

（三）英文品名：

（四）型號：

（五）製造業者名稱：

（六）製造業者所在國家：

（七）許可證所有人：

二、安全監視期間（第一期監視起始日不得遲於發證日，並以每半年為一期）

全程監視期：　年　月　日～　年　月　日

第一期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第二期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第三期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第四期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第五期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第六期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日

三、資料整理（如國外資料統計時間與國內監視期間範圍不同，應另外說明）

（一）國內、外使用人數

監視期間	推估使用人數(或次數)	
	國內	國外
第一期		
第二期		
第三期		
第四期		
第五期		
第六期		
總人數		

Appendix 1

Drug-Eluting Stents (DES)

(This form must be filled out in traditional Chinese, with detailed explanations, and items cannot be omitted or reduced. See "Appendix".)

(If the attached documents are in languages other than traditional Chinese and English, a Chinese-English translation must be provided.)

1. Medical Device Product Information

(1) License Number:

(2) Chinese Product Name:

(3) English Product Name:

(4) Model Number:

(5) Manufacturer's Name:

(6) Country of Manufacture:

(7) License Holder:

2. Safety Surveillance Period (The starting date of the first phase of data collection cannot be earlier than the market launch date; note: surveillance phases cannot stop mid-year)

Overall Surveillance Period: From Year Month Day to Year Month Day

- Data Collection Phase 1: From Year Month Day to Year Month Day Deadline: Year Month Day
- Data Collection Phase 2: From Year Month Day to Year Month Day Deadline: Year Month Day
- Data Collection Phase 3: From Year Month Day to Year Month Day Deadline: Year Month Day
- Data Collection Phase 4: From Year Month Day to Year Month Day Deadline: Year Month Day
- Data Collection Phase 5: From Year Month Day to Year Month Day Deadline: Year Month Day
- Data Collection Phase 6: From Year Month Day to Year Month Day Deadline: Year Month Day

3. Data Summary (If data collection period and usage period are inconsistent, please explain)

(1) Estimated Domestic and Foreign Usage

Estimated Number of Users (Provide numerical estimate)

Surveillance Phase	Domestic	Foreign
Phase 1		
Phase 2		
Phase 3		
Phase 4		
Phase 5		
Phase 6		
Total		

Page 221

Translated by RegDesk AI

（二）國內執行機構累積使用情形

醫事機構層級	販售數量	推估使用人數(或次數)
總數		

*若不敷使用請自行增加欄位

（三）國內、外不良事件件數（非嚴重不良事件應包括顧客申訴）

屬性	嚴重不良事件		非嚴重不良事件	
	國內	國外	國內	國外
第一期				
第二期				
第三期				
第四期				
第五期				
第六期				
總件數				

四、不良事件資料收集（請將本期不良事件內容以條列式呈現）

（一）國內醫療器材嚴重不良事件

（二）國內醫療器材非嚴重不良事件

（三）國外醫療器材嚴重不良事件

（如有通報至國外主管機關之不良事件，請特別註明）

（四）國外醫療器材非嚴重不良事件

（五）國內、外學術期刊文獻及學術研討會上發表之病例報告

五、國內使用 DES 個案整理

（DES 使用個案資料如附錄一，使用醫療機構如附錄二）

(2) Domestic Implementation of Device Usage Conditions

Medical Institution Level	Sales Quantity	Estimated Number of Users (in words)
Total		

*Please add rows if insufficient.

(3) Domestic and International Adverse Event Cases (Serious and Non-serious Adverse Events should be reported separately)

Attribute	Serious Adverse Events		Non-serious Adverse Events	
Domestic	International		Domestic	International
First Phase				
Second Phase				
Third Phase				
Fourth Phase				
Fifth Phase				
Sixth Phase				
Total				

IV. Adverse Event Data Collection (Please state different adverse events separately as necessary)

(1) Domestic medical device-related serious adverse events

(2) Domestic medical device-related non-serious adverse events

(3) International medical device-related serious adverse events

(If reported to international competent authority, please specify)

(4) International medical device-related non-serious adverse events

(5) Domestic and international academic journal literature and academic conference presentations of case reports

V. Domestic DES Usage Case Management

(DES usage case data is attached as Appendix 1. Usage medical institutions as Appendix 2.)

222

Translated by RegDesk AI

附錄一：DES 使用者資料

（一）病人代碼
（二）醫事機構
（三）手術醫師
（四）植入日期：_____年_____月_____日
（五）病人性別
（六）病人年齡
（七）監視項目及執行情形：

表格 A

監視項目	手術前		手術後	
	是/否	日期	是/否	日期
血管造影				
心電圖				

表格 B

抗血栓藥物	手術前		手術後	
	開始日期	用法及劑量	開始日期	用法及劑量
Aspirin				
Ticlopidine				
Clopidogrel				
Dipyridamole				
其他				

Appendix 1: DES User Information

(1) Patient Code

(2) Medical Institution

(3) Attending Physician

(4) Implantation Date: ____ Year ___ Month ____ Day

(5) Patient Gender

(6) Patient Age

(7) Monitoring Items and Implementation:

Table A

Monitoring Item	Before Surgery		After Surgery	
Angiography	Yes/No	Date	Yes/No	Date
ECG				

Table B

Anticoagulant Drugs	Before Surgery		After Surgery	
	Start Date	Method & Dose	Start Date	Method & Dose
Aspirin				
Ticlopidine				
Clopidogrel				
Dipyridamole				
Others				

223

Translated by RegDesk AI

（八）手術後追蹤：

表格 C

追蹤情形	定期追蹤：□ 有　　□ 無
	追蹤間隔時間：_____週/月
追蹤期間異常發現	a)日期： 異常情形（包括併發症，請詳細描述）：
	b）日期： 異常情形（包括併發症，請詳細描述）：
	c）日期： 異常情形（包括併發症，請詳細描述）：

註：本附錄為一式二份存於醫療機構及醫療器材商，每位使用病人均需分別填寫。若欄位不足，請自行增加欄位。本附錄應保存至監視期間屆滿後五年供備查。

(VIII) Post-Surgery Follow-up:

Form C

Follow-up Status

Regular Follow-up: □ Yes □ No

Follow-up Interval: _____ weeks/months

Follow-up Period Abnormalities

a) Date:

Abnormality (including complication, please describe in detail):

b) Date:

Abnormality (including complication, please describe in detail):

c) Date:

Abnormality (including complication, please describe in detail):

Note: This record is in duplicate, with one copy each retained by the medical institution and the medical device manufacturer. Each user and patient must be recorded separately. If there are insufficient fields, please add more as needed. This record should be kept for up to five years for future reference.

Translated by RegDesk AI

附錄二：本次報告監視期間的 DES 使用情形統計表

DES 使用總支數	執行機構使用情形	
	醫事機構名稱	使用支數

註：本附錄為必繳交項目。若欄位不足，請自行增加欄位。

Appendix 2: Statistical Table of DES Usage During the Supervision Period of This Report

Total Number of DES Used	Utilization by Institutions
Name of Institution or Agency	Number of Uses

Note: This appendix is a mandatory submission item. If there are insufficient rows, please add more rows yourself.

Translated by RegDesk AI

附件二

第一個核准上市國為我國之第三等級醫療器材

（請以正體中文依格式填寫及詳述說明，不可自行刪減項目或僅寫「詳見附件」。
檢附之附件資料如非正體中文或英文者，應另附正體中文或英文譯本。）

一、醫療器材產品資料

（一）許可證字號：

（二）中文品名：

（三）英文品名：

（四）型號：

（五）製造業者名稱：

（六）製造業者所在國家：

（七）許可證所有人：

二、安全監視期間（第一期監視起始日不得遲於發證日，並以每半年為一期）

全程監視期：　年　月　日～　年　月　日

第一期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第二期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第三期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第四期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第五期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第六期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日

三、資料整理（如國外資料統計時間與國內監視期間範圍不同，應另外說明）

（一）國內、外使用人數

監視期間	推估使用人數(或次數)	
	國內	國外
第一期		
第二期		
第三期		
第四期		
第五期		
第六期		
總人數		

Appendix 2

A medical device approved abroad as a Class 3 medical device in China

(For more details, refer to the "Supplementary Instructions" for filling out this form. This form should not be altered without permission.)

1. Medical Device Product Information

(1) License Number:

(2) Chinese Name:

(3) English Name:

(4) Model:

(5) Manufacturer’s Name:

(6) Country of Manufacturer:

(7) License Holder:

2. Safety Surveillance Period

(Start date for each period must not exceed approved surveillance period; note that each period is half a year)

Overall Surveillance Period: Year Month Day □ Year Month Day Closed Evaluation Deadline: Year Month Day

First Period Start Date: Year Month Day □ Year Month Day Closed Evaluation Deadline: Year Month Day

Second Period Start Date: Year Month Day □ Year Month Day Closed Evaluation Deadline: Year Month Day

Third Period Start Date: Year Month Day □ Year Month Day Closed Evaluation Deadline: Year Month Day

Fourth Period Start Date: Year Month Day □ Year Month Day Closed Evaluation Deadline: Year Month Day

Fifth Period Start Date: Year Month Day □ Year Month Day Closed Evaluation Deadline: Year Month Day

Sixth Period Start Date: Year Month Day □ Year Month Day Closed Evaluation Deadline: Year Month Day

3. Data Summary

(If data analysis period is different from domestic surveillance periods, please provide a separate explanation)

(1) Domestic and Foreign User Numbers

Surveillance Period	Number of Designated Users (unit: person)	
	Domestic	Abroad
First Period		
Second Period		
Third Period		

Translated by RegDesk AI

Fourth Period

Fifth Period

Sixth Period

Total Number of People

226

Translated by RegDesk AI

（二）國內執行機構累積使用情形（如為租借請註明）

醫事機構層級	販售數量	推估使用人數(或次數)
總數		

*若不敷使用請自行增加欄位

（三）國內、外不良事件件數（非嚴重不良事件應包括顧客申訴）

屬性	嚴重不良事件		非嚴重不良事件	
	國內	國外	國內	國外
第一期				
第二期				
第三期				
第四期				
第五期				
第六期				
總件數				

四、不良事件資料收集（請將本期不良事件內容以條列式呈現）

（一）國內醫療器材嚴重不良事件

（二）國內醫療器材非嚴重不良事件

（三）國外醫療器材嚴重不良事件

（如有通報至國外主管機關之不良事件，請特別註明）

（四）國外醫療器材非嚴重不良事件

（五）國內、外學術期刊文獻及學術研討會上發表之病例報告

(2) Usage of the Execution Agency's Border (Please specify if not applicable)

Medical Institution Level	Number Sold	Estimated Usage Personnel (or Number of Times)
Total		

*If no scales, please fill in the ordering unit separately

(3) Number of Domestic and Foreign Adverse Events (Non-serious adverse events are to be included in total statistics)

Attribute	Serious Adverse Events		Non-serious Adverse Events	
	Domestic	Abroad	Domestic	Abroad
Period 1				
Period 2				
Period 3				
Period 4				
Period 5				
Period 6				
Total				

4. Collection of Adverse Event Information (Please attach relevant documentation if there are severe adverse events in each period)

(1) Severe Adverse Events of Domestic Medical Devices

(2) Non-severe Adverse Events of Domestic Medical Devices

(3) Severe Adverse Events of Foreign Medical Devices

(If reported to foreign authorities with adverse events, specify)

(4) Non-severe Adverse Events of Foreign Medical Devices

(5) Case reports published in domestic and foreign journals and literature, presented at academic conferences

227

Translated by RegDesk AI

附件三

經陰道手術修補網

（請以正體中文依格式填寫及詳述說明，不可自行刪減項目或僅寫「詳見附件」。
檢附之附件資料如非正體中文或英文者，應另附正體中文或英文譯本。）

一、醫療器材產品資料

（一）許可證字號：

（二）中文品名：

（三）英文品名：

（四）型號：

（五）製造業者名稱：

（六）製造業者所在國家：

（七）許可證所有人：

二、安全監視期間（第一期監視起始日不得遲於發證日，並以每半年為一期）

全程監視期：　年　月　日～　年　月　日

第一期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第二期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第三期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第四期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第五期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日
第六期資料起訖：　年　月　日～　年　月　日	繳交期限：　年　月　日

三、資料整理（如國外資料統計時間與國內監視期間範圍不同，應另外說明）

（一）國內、外使用人數

監視期間	推估使用人數(或次數)	
	國內	國外
第一期		
第二期		
第三期		
第四期		
第五期		
第六期		
總人數		

Appendix Three

Supplementary Form for Colonoscopy Procedure

(Please fill in according to the notes, instructions, and examples in the main form. Do not write responses in areas marked “for official use only.” Attach necessary documents, main form Chinese and English texts as well as certified translations if applicable.)

I. Medical Device Product Information

(1) License Number:

(2) Chinese Product Name:

(3) English Product Name:

(4) Model Number:

(5) Manufacturer Name:

(6) Manufacturer Country:

(7) License Holder:

II. Safety Monitoring Period (The start date of the first monitoring period must not exceed the approval date; subsequent periods are to be conducted annually.)

Overall Monitoring Period: Year Month Day to Year Month Day

First Period Start Date: Year Month Day to Year Month Day Approval Date: Year Month Day

Second Period Start Date: Year Month Day to Year Month Day Approval Date: Year Month Day

Third Period Start Date: Year Month Day to Year Month Day Approval Date: Year Month Day

Fourth Period Start Date: Year Month Day to Year Month Day Approval Date: Year Month Day

Fifth Period Start Date: Year Month Day to Year Month Day Approval Date: Year Month Day

Sixth Period Start Date: Year Month Day to Year Month Day Approval Date: Year Month Day

III. Data Management (If the calculation method for foreign data differs from that of domestic data, please explain separately.)

(1) Number of Domestic and Foreign Users

Monitoring Period	Estimated Number of Users (Maximum)	
Period 1	Domestic	Foreign
Period 2	Domestic	Foreign
Period 3	Domestic	Foreign
Period 4	Domestic	Foreign
Period 5	Domestic	Foreign
Period 6	Domestic	Foreign
Total		

228

Translated by RegDesk AI

（二）國內執行機構累積使用情形

醫事機構層級	販售數量	推估使用人數(或次數)
總數		

*若不敷使用請自行增加欄位

（三）國內、外不良事件（非嚴重不良事件應包括顧客申訴）

屬性	嚴重不良事件				非嚴重不良事件			
	國內		國外		國內		國外	
	件數	比例(件數/使用數量)	件數	比例(件數/使用數量)	件數	比例(件數/使用數量)	件數	比例(件數/使用數量)
第一期								
第二期								
第三期								
第四期								
第五期								
第六期								
總件數								

四、不良事件資料收集（請將本期不良事件內容以條列式呈現）

（一）國內醫療器材嚴重不良事件

（二）國內醫療器材非嚴重不良事件

（三）國外醫療器材嚴重不良事件

（如有通報至國外主管機關之不良事件，請特別註明）

（四）國外醫療器材非嚴重不良事件

（五）國內、外學術期刊文獻及學術研討會上發表之病例報告

(2) Domestic Executing Agency Cumulative Usage Situation

Medical Device Classification/Level	Sales Quantity	Estimated User Count (Person-times)
—————		
—————		
—————		
Total		

*If there are more levels, please add more rows

(3) Domestic and Foreign Adverse Events (Non-severe adverse events also include litigation cases)

Severe Adverse Events

Domestic | Foreign

Attr...	Quantity/Ratio (Quantity/Usage)	Quantity/Ratio (Quantity/Usage)	Quantity/Ratio (Quantity/Usage)	Quantity/Ratio (Quantity/Usage)
Period 1				
Period 2				
Period 3				
Period 4				
Period 5				
Period 6				
Total Count				

Four: Adverse Event Data Collection (If no new severe adverse events occurred during the period, please indicate as none)

(1) Domestic Medical Device Severe Adverse Events

(2) Domestic Medical Device Non-Severe Adverse Events

(3) Foreign Medical Device Severe Adverse Events

(If reported by a foreign regulatory agency, please specify in detail)

(4) Foreign Medical Device Non-Severe Adverse Events

(5) Cases Published in Domestic and Foreign Journals and Presented at Academic Conferences

229

Translated by RegDesk AI

五、國內使用個案整理統計表

表 1：本次報告期間不良事件數

使用總數量	醫事機構使用情形			
	醫事機構名稱	使用數量	不良事件數	比例(件數/使用數量)

表 2：本次報告期間使用醫療機構分布

	醫事機構數量	使用數量	不良事件數	比例(件數/使用數量)
醫學中心				
區域醫院				
地區醫院				
診所				
總計				

5. Domestic Usage Case Statistics Table

Table 1: Number of Adverse Events During This Reporting Period

Total Usage Volume	Medical Institution Name	Usage Volume	Number of Adverse Events	Ratio (Number of Cases / Usage Volume)

Table 2: Distribution of Medical Institutions Used During This Reporting Period

Number of Medical Institutions	Usage Volume	Number of Adverse Events	Ratio (Number of Cases / Usage Volum
Medical Center			
Regional Hospital			
Local Hospital			
Clinic			
Total			

230

Translated by RegDesk AI

表 3：經陰道手術修補網使用者資料

醫事機構			
病人代碼（去識別化）			
植入日期			
不良反應（請勾選）		發生日期	事件描述、後續處置及說明
	一般手術併發症		
	感染		
	疼痛		
	出血		
	過敏反應		
	臟器穿孔		
	網膜收縮		
	網膜糜爛/突出		
	復發性脫垂		
	其他		

註：若欄位不足，請自行增加欄位。

Table 3: Post-Inguinal Hernia Surgery Mesh Usage Data

Medical Institution

Patient Code (De-identified)

Implantation Date

Adverse Reactions (Please check)	Occurrence Date	Event Description, Follow-up Actions and Explanation
General Surgical Complications		
Infection		
Pain		
Bleeding		
Allergic Reaction		
Organ Perforation		
Mesh Contracture		
Mesh Bulging/Protrusion		
Recurrent Hernia		
Others		

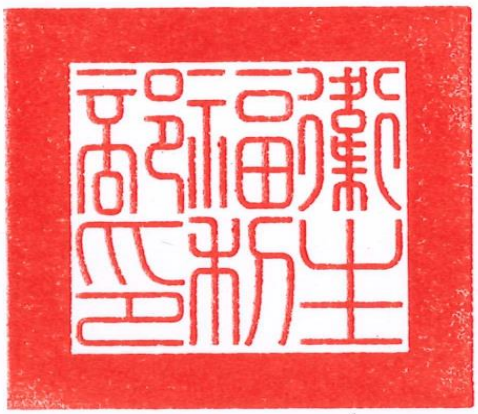
Note: If there are insufficient fields, please add your own.

Translated by RegDesk AI

【使用醫療器材蒐集、處理或利用個人資訊者，其替代書面同意之方式】

檔　　號：
保存年限：

衛生福利部　公告



發文日期：中華民國110年4月15日
發文字號：衛授食字第1101602439號
附件：

裝

主旨：訂定「使用醫療器材蒐集、處理或利用個人資訊者，其替代書面同意之方式」，並自中華民國一百十年五月一日生效。

訂

依據：醫療器材管理法第八十一條。

公告事項：研究機構、醫事機構或醫療器材商，因醫療器材之使用特性，蒐集、處理或利用個人資料保護法第六條之個人資訊者，其書面同意方式，得依電子簽章法之規定，以電子文件為之。

線

部長陳時中

第一頁（共一頁）

「Method for obtaining consent from individuals when collecting, processing, or using personal information with medical devices, and its alternative method of consent」

Ministry of Health and Welfare Announcement

Document Date: April 15, 2021

Document Number: Shu-Zi-Wei-Zi-No. 1101602439

Attachment: None

Subject: Establishing the "Method for obtaining consent from individuals when collecting, processing, or using personal information with medical devices, and its alternative method of consent," effective May 1, 2021.

According to: Article 11 of the Medical Devices Administration Act.

Announcement Details: Research institutions, organizations, or medical device traders must, due to the specifications and attributes of medical devices, collect, process, or use personal information as outlined in Article 6 of the Personal Information Protection Act. For obtaining consent forms, electronic signatures are allowed as per regulations, and electronic documents will suffice.

Minister: Chen Shih-Chung

Page 1 (Total of 1 page)

Translated by RegDesk AI