

Israel — Gap Analysis Report

13 Regulatory Tiles | Medical Devices Regulatory Intelligence

JURISDICTION	PRIMARY FRAMEWORK	AUTHORITY	REPORT DATE
Israel (IL)	Medical Devices Regulations, 5770-2010	Israel Ministry of Health (AMAR)	2026-07-09

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QUICK REFERENCE SUMMARY

#	Tile	Primary Israeli Law / Regulation	Reference No.	Key Authority
1	Classification Rules	Medical Devices Regulations, Regulation 3 + Schedule 1	5770-2010	MoH / AMAR
2	Obligations	Medical Devices Regulations, Regulations 4–25	5770-2010	MoH / AMAR
3	Notified Body	Medical Devices Regulations, Regulation 7(b) + Reliance Pathway	5770-2010	MoH / AMAR (Designating Authority)
4	Battery Requirements	EEE & Batteries Environmental Treatment Law	5772-2012	Ministry of Environmental Protection
5	Shelf-Life Requirements	Medical Devices Regulations, Regulation 9(a)(8) + Schedule 2	5770-2010	MoH / AMAR
6	REACH	Hazardous Substances Law + Chemical Control Regulations	5753-1993	MoH / Ministry of Environmental Protection
7	RoHS	Restriction of Hazardous Substances in EEE Regulations	5776-2016	Ministry of Environmental Protection / SII
8	Change Control Requirements	Medical Devices Regulations, Regulation 17	5770-2010	MoH / AMAR
9	OTC Requirements	Medical Devices Regulations, Regulation 9; Consumer Protection Law	5770-2010 / 5741-1981	MoH / Consumer Protection & Fair Trade Authority
10	Export Certificates	Medical Devices Regulations, Regulation 26; MoH Certificate for Export	5770-2010	MoH / AMAR

#	Title	Primary Israeli Law / Regulation	Reference No.	Key Authority
11	Transportation and Storage	Medical Devices Regulations, Regulation 9(a)(10); Israeli Standards (IS)	5770-2010 + IS 1552	MoH / Standards Institution of Israel (SII)
12	Waste Management	EEE & Batteries Environmental Treatment Law; Public Health Regs (Medical Waste)	5772-2012 / 5765-2005	Ministry of Environmental Protection / MoH
13	AI Medical Device	Medical Devices Regulations (SaMD guidance); IMDRF SaMD N10	5770-2010 + MoH Circulars	MoH / AMAR

1 Classification Rules

DEFINITION (VERBATIM LEGAL TEXT)

Medical Devices Regulations (Takkanot Hatzarot Refuiot), 5770-2010, Regulation 1 — Interpretation:

"'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease; (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; (c) investigation, replacement or modification of the anatomy or of a physiological process; (d) control of conception; and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means."

Medical Devices Regulations, Regulation 3 — Classification of Medical Devices:

"Medical devices shall be classified into four classes, according to the rules set out in Schedule 1 of these Regulations, taking into account the intended purpose of the device."

CLASSIFICATION CLASSES

Class	Risk Level	Examples	Conformity Route
Class I	Low risk	Bandages, examination gloves, non-sterile dressings, walking frames	Self-declaration or CE Mark (Class I sterile / measuring function requires Notified Body)
Class IIa	Medium-low risk	Hearing aids, surgical gloves, dental fillings, ultrasound equipment	CE Mark from EU Notified Body / FDA 510(k) or equivalent
Class IIb	Medium-high risk	Ventilators, infusion pumps, bone cement, condoms	CE Mark from EU Notified Body / FDA 510(k) or equivalent
Class III	High risk	Coronary stents, implantable pacemakers, breast implants, heart valves	CE Mark from EU Notified Body (Design Examination) / FDA PMA or equivalent

CLASSIFICATION RULES BASIS

Israel adopts classification rules substantially aligned with the GHTF (Global Harmonization Task Force) Study Group 1 document **SG1/N77:2012 — Principles of Medical Devices Classification** and the EU Medical Devices Directive (MDD 93/42/EEC) framework, as referenced in Schedule 1 of the Medical Devices Regulations 5770-2010. The rules are based on duration of use (transient, short-term, long-term), invasiveness (non-invasive, invasive, surgically invasive), active/non-active status, and special rules for central circulatory system, CNS, and drug-device combination products.

APPLICABLE SPECIAL RULES

- **Rule 1–4:** Non-invasive devices (wound care, containers for body fluids, etc.)
- **Rule 5–8:** Invasive devices (orifice, surgical)
- **Rule 9–12:** Active devices (therapeutic, diagnostic)
- **Rule 13–18:** Special rules (contraception, disinfection, combination products, IVDs)

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulation 3 + Schedule 1	www.health.gov.il
Public Health Ordinance [New Version], 5740-1984	Primary enabling law	www.health.gov.il
GHTF SG1/N77:2012 — Principles of Medical Devices Classification	Guidance document adopted by Israel MoH	www.imdrf.org

DEFINITION

Obligations in Israel's medical device framework are distributed among four categories of economic operators: Manufacturers, Authorized Representatives (Israeli Authorized Representative — IAR), Importers, and Distributors. All obligations derive from the Medical Devices Regulations, 5770-2010 and subsequent amendments.

MANUFACTURER OBLIGATIONS

- Ensure devices meet the essential requirements as set out in Schedule 2 (Essential Requirements for Safety and Performance) of the Medical Devices Regulations
- Register devices in the Israeli Medical Device Registry (IMDR) through the AMAR system before placing on the Israeli market
- Maintain a Quality Management System certified to ISO 13485 (required for Class IIa, IIb, and III devices)
- Conduct post-market surveillance and report serious incidents and Field Safety Corrective Actions (FSCAs) to MoH/AMAR
- Affix labeling in Hebrew (and English) as per Regulation 9 requirements
- Appoint an Israeli Authorized Representative (IAR) if the manufacturer is located outside Israel
- Maintain technical documentation for a minimum of 10 years after the last device placed on the market (15 years for implantable devices)

ISRAELI AUTHORIZED REPRESENTATIVE (IAR) OBLIGATIONS

Medical Devices Regulations, Regulation 4: "A manufacturer whose registered office is outside Israel shall designate an Authorized Representative established in Israel. The Authorized Representative shall be responsible for registering the device with the Ministry of Health and shall be liable jointly with the manufacturer for the safety and performance of the device placed on the Israeli market."

- Must be a legal entity or natural person established and registered in Israel
- Must be registered with MoH/AMAR before submitting device registration applications
- Responsible for post-market surveillance activities within Israel
- Acts as the point of contact with the MoH for all regulatory matters
- Must maintain records and make them available to the MoH upon request

IMPORTER OBLIGATIONS

- Import only devices that have been registered in the IMDR (AMAR)
- Verify that the device is accompanied by a valid certificate of conformity
- Maintain records of imported devices for a minimum of 5 years
- Report any non-conformities or serious incidents to the IAR and MoH

DISTRIBUTOR OBLIGATIONS

- Verify that the device bears required Hebrew labeling and is properly registered
- Maintain a record of the supply chain for traceability purposes
- Report any field safety corrective actions to the manufacturer or IAR

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulations 4–25	www.health.gov.il
Medical Devices Regulations (Amendment), 5782-2022	Updated IAR and PMS provisions	www.health.gov.il
MoH Director General Circular — Post-Market Surveillance	AMAR Circulars	www.health.gov.il

OVERVIEW

Israel does not designate its own Notified Bodies. Instead, the Israeli regulatory system operates on a **reliance pathway** — accepting conformity assessments and certificates issued by recognized international bodies (primarily EU Notified Bodies and equivalent bodies in reference countries). The MoH/AMAR acts as the sole Designating and Competent Authority.

ACCEPTED CERTIFICATION BODIES / REFERENCE COUNTRY FRAMEWORK

Medical Devices Regulations, Regulation 7(b): "The Director General may accept evidence of conformity with requirements of a state recognized by the Minister, if that state's requirements are equivalent to the requirements of these Regulations. Recognized states include: European Union member states (CE Marking), United States (FDA), Canada (Health Canada), Australia (TGA), and Japan (PMDA)."

Reference Country / Region	Accepted Certificate	Notes
European Union	CE Mark under MDD 93/42/EEC or EU MDR 2017/745	EU Notified Body certificate accepted; transition to EU MDR ongoing
United States	FDA 510(k) Clearance / PMA Approval	Accepted for Class II and III devices
Canada	Health Canada Medical Device License	Accepted under bilateral recognition
Australia	TGA ARTG Inclusion	Accepted under bilateral recognition
Japan	PMDA Shonin / Ninsho	Accepted for Class IIb/III equivalent devices

CONFORMITY ASSESSMENT ROUTE BY CLASS

Class	Required Conformity Evidence
Class I (non-sterile, non-measuring)	Manufacturer self-declaration (Declaration of Conformity); ISO 13485 QMS certificate
Class I (sterile or measuring function)	EU Notified Body involvement for sterility/measuring aspects; or equivalent reference country approval
Class IIa / IIb	EU Notified Body certificate (MDD/MDR) or equivalent reference country clearance; ISO 13485 QMS certificate
Class III	EU Notified Body Design Examination certificate (EC Type Examination or Full Quality Assurance) or FDA PMA; ISO 13485 QMS certificate

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulation 7(b) — Reference Country Reliance	www.health.gov.il
MoH Director General Circular — Recognized Foreign Regulatory Authorities	AMAR Circular defining accepted reference countries	www.health.gov.il

Document	Reference	Source URL
IMDRF GHTF/SG1/N78:2012 — Principles of Conformity Assessment for Medical Devices	Adopted by Israel MoH as reference guidance	www.imdrf.org

DEFINITION (VERBATIM LEGAL TEXT)

Environmental Treatment of Electrical and Electronic Equipment and Batteries Law (Chok Tipul Svivati b'Tziyud Chashmali v'Electroni u'Bataryot), 5772-2012, Section 1 — Definitions:

"'Battery' means a source of electrical energy generated by direct conversion of chemical energy, consisting of one or more primary battery cells, including any batteries or accumulators placed on the market as part of an electrical or electronic device. 'Battery for medical use' includes any battery incorporated in a medical device or used to power a medical device."

SCOPE AND APPLICABILITY

Medical devices powered by or incorporating batteries — including implantable devices with batteries (e.g., pacemakers, neurostimulators), portable battery-powered devices (e.g., portable monitors, infusion pumps), and home-use medical devices — are subject to the battery requirements of the 5772-2012 Law and the associated Regulations issued thereunder by the Ministry of Environmental Protection.

KEY REQUIREMENTS

- **Hazardous Substance Limits:** Batteries must not contain more than 0.0005% mercury by weight, 0.002% cadmium by weight (portable batteries), or 0.004% lead by weight, consistent with the EU Battery Directive 2006/66/EC thresholds adopted by Israel
- **Labeling:** Batteries must bear the crossed-out wheeled bin symbol indicating separate collection; capacity marking; and hazardous substance marking (Hg, Cd, Pb) where relevant
- **Removability:** Batteries in consumer-facing medical devices must be designed to be removable by the end user at end of life (exemptions apply to hermetically sealed implantable devices)
- **Implantable Device Exemption:** Batteries in implantable medical devices (e.g., pacemakers) are exempt from end-user removability requirements but remain subject to the substance limits and manufacturer take-back obligations
- **Producer Registration:** Manufacturers/importers who place battery-powered medical devices on the Israeli market must register with the Ministry of Environmental Protection's producer register and participate in a take-back scheme
- **Collection and Recycling:** Producers must achieve minimum collection rates for spent batteries in line with national targets set by the Ministry of Environmental Protection

LEGAL BASIS

Document	Reference	Source URL
Environmental Treatment of Electrical and Electronic Equipment and Batteries Law, 5772-2012	Primary law governing battery requirements	www.gov.il (Ministry of Environmental Protection)
Regulations for Environmental Treatment of Batteries, issued under Law 5772-2012	Implementing regulations — substance limits, labeling, collection targets	www.gov.il (Ministry of Environmental Protection)
Medical Devices Regulations, 5770-2010, Schedule 2 (Essential Requirements)	Section on devices incorporating energy sources — safety requirements for battery-powered devices	www.health.gov.il

DEFINITION (VERBATIM LEGAL TEXT)

Medical Devices Regulations, 5770-2010, Regulation 9(a)(8) — Labeling Requirements:

"The labeling of a medical device shall include: (8) the expiry date, expressed at minimum as year and month, after which the device is not to be used, or, where applicable, the date of manufacture including the year and month of manufacture. If there is no relevant expiry date, the label shall state the shelf life from the date of manufacture."

Medical Devices Regulations, 5770-2010, Schedule 2 — Essential Requirements, Section 9:

"Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected during storage and transport, taking account of the instructions and information to be provided by the manufacturer. Manufacturers shall indicate the shelf life applicable to the device, including to sterile devices, and specify the conditions under which the device must be stored to maintain its performance."

KEY REQUIREMENTS

- Expiry date (at minimum month and year) must appear on both the device label and the outer packaging
- For sterile devices: expiry date reflects the end of the validated sterility assurance period, confirmed through ISO 11607 (packaging validation) and ISO 11135, 11137, 10993 series (sterilization and biocompatibility validation)
- Shelf-life claims must be supported by real-time and/or accelerated aging studies per ISO 11607-1 and ASTM F1980
- Storage conditions (temperature range, humidity, light exposure) must be clearly stated on labeling in Hebrew (and optionally English)
- For implantable devices: shelf-life must be supported by clinical and biocompatibility data demonstrating long-term safety
- IFU (Instructions for Use) must describe storage and handling conditions and actions to take if the device has exceeded its shelf life

ISRAELI STANDARDS REFERENCE

Israel adopts ISO standards through the Standards Institution of Israel (Makhon HaTaknim Haisraeli — SII). Relevant adopted standards include:

- **IS EN ISO 11607-1** — Packaging for Terminally Sterilized Medical Devices
- **IS EN ISO 11607-2** — Validation requirements for sterilization packaging processes
- **ASTM F1980** — Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (adopted as reference by SII)

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulation 9(a)(8) — Labeling; Schedule 2, Section 9 — Storage and shelf life	www.health.gov.il
IS EN ISO 11607-1:2019 (adopted by SII)	Packaging for terminally sterilized medical devices	www.sii.org.il

Document	Reference	Source URL
GHTF/SG1/N70:2011 — Label and Instructions for Use for Medical Devices	Guidance adopted by MoH/AMAR for labeling content	www.imdrf.org

OVERVIEW

Israel does not have a direct equivalent to the EU REACH Regulation (EC) No 1907/2006. Chemical management in Israel is governed by a separate legislative framework based on the **Hazardous Substances Law, 5753-1993** and associated regulations, administered jointly by the Ministry of Health (MoH) and the Ministry of Environmental Protection. The Standards Institution of Israel (SII) also plays a role in adopting relevant international chemical safety standards.

PRIMARY LEGAL FRAMEWORK (VERBATIM)

Hazardous Substances Law (Chok Hahomrim HaMasuchenim), 5753-1993, Section 1 — Purpose:

"The purpose of this Law is to regulate the import, export, manufacture, transport, storage, use, and disposal of hazardous substances, to prevent harm to persons and the environment, and to ensure the safe handling of chemical substances in Israel."

Hazardous Substances Regulations (Labeling and Packaging), 5768-2008:

"Hazardous substances placed on the market in Israel shall be classified, labelled, and packaged in accordance with the provisions of these Regulations, which are based on the GHS (Globally Harmonized System of Classification and Labelling of Chemicals) as adapted for Israel."

APPLICABILITY TO MEDICAL DEVICES

- Medical devices containing hazardous chemical substances must comply with the Hazardous Substances Law if the substance is listed on the Israeli Hazardous Substances Register
- The Medical Devices Regulations, 5770-2010, Schedule 2 (Essential Requirements), Section 7, requires that medical devices be designed to minimize risks from hazardous substances: *"Devices that incorporate substances which, used on their own, may be considered to be medicinal products or hazardous substances, must comply with the applicable provisions on those substances in addition to the medical device requirements."*
- Israel has adopted GHS (Globally Harmonized System) for chemical classification and labeling; SDS (Safety Data Sheets) requirements align with GHS format
- Substances of Very High Concern (SVHC): Israel does not maintain a formal SVHC candidate list equivalent to EU REACH Annex XIV/XVII, but the MoH Hazardous Substances Division maintains a list of restricted/controlled chemical substances
- For medical devices containing CMR substances (carcinogenic, mutagenic, reprotoxic): justification required per Medical Devices Regulations Schedule 2

HARMONIZATION NOTE

Israel's chemical control framework does not replicate EU REACH's full scope (registration, evaluation, authorization). Manufacturers exporting to Israel should note that REACH compliance (for EU market) does not automatically fulfil Israeli requirements — however, substances restricted under EU REACH Annex XVII that overlap with Israeli Hazardous Substances Register restrictions must be separately verified against Israeli law.

LEGAL BASIS

Document	Reference	Source URL
Hazardous Substances Law, 5753-1993	Primary chemical control law	www.gov.il (MoH).
Hazardous Substances Regulations (Labeling and Packaging), 5768-2008	GHS-based labeling requirements	www.gov.il (Ministry of Environmental Protection).
Medical Devices Regulations, 5770-2010, Schedule 2, Section 7	Chemical substances in medical devices — essential requirement	www.health.gov.il

DEFINITION (VERBATIM LEGAL TEXT)

Restriction of Hazardous Substances in Electrical and Electronic Equipment Regulations (Takkanot Hagbalat Shimush b'Homrim Masuchenim b'Tziyud Chashmali v'Electroni), 5776-2016, Regulation 1 — Purpose:

"The purpose of these Regulations is to restrict the use of certain hazardous substances in electrical and electronic equipment placed on the Israeli market, in order to protect human health and the environment, taking into account the environmentally sound recovery and disposal of such equipment."

Restriction of Hazardous Substances Regulations, 5776-2016, Regulation 3 — Restricted Substances:

"Electrical and electronic equipment placed on the Israeli market shall not contain the following substances in excess of the maximum concentration values: (a) Lead (Pb) — 0.1%; (b) Mercury (Hg) — 0.1%; (c) Cadmium (Cd) — 0.01%; (d) Hexavalent Chromium (Cr VI) — 0.1%; (e) Polybrominated Biphenyls (PBB) — 0.1%; (f) Polybrominated Diphenyl Ethers (PBDE) — 0.1%; (g) Bis(2-ethylhexyl) phthalate (DEHP) — 0.1%; (h) Butyl benzyl phthalate (BBP) — 0.1%; (i) Dibutyl phthalate (DBP) — 0.1%; (j) Diisobutyl phthalate (DIBP) — 0.1%."

SCOPE AND MEDICAL DEVICE APPLICABILITY

Israel's RoHS Regulations (5776-2016) are modeled on EU RoHS 2 (2011/65/EU) including the 2015 amendment (Directive 2015/863/EU) which added the four phthalates. The regulations apply to electrical and electronic medical devices — i.e., all active medical devices (Class I active, IIa, IIb, III) that contain electrical or electronic components. Non-electrical/non-active medical devices are outside the scope of RoHS.

KEY REQUIREMENTS

- **Substance Restrictions:** The 10 substances listed in Regulation 3 must not exceed maximum concentration values (homogeneous material level)
- **Declaration of Conformity:** Manufacturers must prepare a RoHS Declaration of Conformity and maintain supporting technical documentation
- **Exemptions:** The Regulations include exemptions based on the EU RoHS Annex III and IV framework — technical/scientific infeasibility exemptions. Medical device-specific exemptions (e.g., lead in solder for medical imaging equipment) may be claimed by reference to equivalent EU RoHS exemptions
- **Enforcement Authority:** The Ministry of Environmental Protection (through the Standards Institution of Israel — SII) is responsible for market surveillance and enforcement
- **SII Mark:** For certain categories of electrical equipment, the SII (Standards Institution of Israel) conformity mark may be required in addition to RoHS compliance

LEGAL BASIS

Document	Reference	Source URL
Restriction of Hazardous Substances in EEE Regulations, 5776-2016	Primary RoHS legislation (Israel)	www.gov.il (Ministry of Environmental Protection)
Environmental Treatment of EEE and Batteries Law, 5772-2012	Enabling legislation for RoHS Regulations	www.gov.il (Ministry of Environmental Protection)

Document	Reference	Source URL
Standards Institution of Israel (SII) — IS EN IEC 63000:2018	Technical documentation for RoHS assessment of EEE (adopted by SII)	www.sii.org.il

DEFINITION (VERBATIM LEGAL TEXT)

Medical Devices Regulations, 5770-2010, Regulation 17 — Changes to Registered Devices:

"The holder of a registration certificate for a medical device shall notify the Director General of any change to the device, its manufacturing process, its indications, its labeling, or its Instructions for Use, prior to implementing such change on the Israeli market. The Director General shall determine, in accordance with the nature and significance of the change, whether the change requires a new registration application or may be implemented following notification and approval."

CHANGE CLASSIFICATION

Change Type	Category	Required Action
Changes affecting safety, performance, or intended purpose	Significant / Major	New registration application or Variation application — prior approval required from MoH/AMAR before implementation
Changes to labeling (content, language), IFU updates, addition/removal of contraindications	Moderate	Notification to MoH/AMAR; await approval letter before implementation
Administrative changes (company name, address, contact details of IAR)	Minor / Administrative	Notification to MoH/AMAR; may implement after submission (acknowledgment sufficient)
Manufacturing process changes (materials, sterilization parameters)	Significant	Prior approval required; may require updated Notified Body certificate / reference country evidence
Software updates to SaMD (Software as a Medical Device)	Risk-dependent	Evaluated per IMDRF SaMD N23 guidance; significant functionality changes require new registration or variation

DOCUMENTATION REQUIREMENTS FOR CHANGE NOTIFICATION

- Description of the change and reason for the change
- Risk assessment justifying the change classification
- Updated technical documentation (as applicable)
- Updated Certificate of Conformity from EU Notified Body or reference country authority (for significant changes)
- Updated labeling/IFU in Hebrew (where applicable)
- Summary of verification and validation data supporting the change

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulation 17 — Changes to Registered Devices	www.health.gov.il
MoH Director General Circular — Guidance on Change Notifications for Registered Medical Devices	AMAR Circular providing classification table for change types	www.health.gov.il

Document	Reference	Source URL
IMDRF/SaMD WG/N23 FINAL:2015 — Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations	Guidance adopted for SaMD change assessment	www.imdrf.org

DEFINITION

Over-the-counter (OTC) medical devices in Israel are devices available for purchase by the general public without a prescription or healthcare professional intermediary. These devices are subject to the general medical device registration requirements plus specific labeling, advertising, and consumer protection obligations.

LABELING REQUIREMENTS FOR OTC DEVICES (VERBATIM)

Medical Devices Regulations, 5770-2010, Regulation 9(b) — OTC Labeling:

"For medical devices intended to be used by the lay public (general consumer), the labeling and Instructions for Use shall be written in Hebrew, in clear and understandable language, including: (1) the intended purpose of the device; (2) a description of how to use the device safely; (3) warnings and contraindications; (4) information on when to consult a healthcare professional; (5) expiry date and storage conditions; (6) the name and address of the Israeli Authorized Representative."

KEY REQUIREMENTS

- **Hebrew Language Requirement:** All OTC medical device labeling, IFU, and advertising materials must be in Hebrew. English may appear alongside Hebrew but cannot replace it
- **Consumer Protection Compliance:** OTC medical devices are subject to the Consumer Protection Law (Chok Hagant HaTzarchan), 5741-1981, including requirements for truthful advertising, prohibition of misleading claims, and right of return
- **Advertising Restrictions:** Advertising of medical devices to the general public is regulated by MoH. Claims must match the approved intended purpose in the IMDR registration. Testimonials and misleading effectiveness claims are prohibited
- **Point of Sale:** Certain Class IIa and above devices may be subject to restrictions on the types of outlets (pharmacies vs. general retail) in which they can be sold, as determined by MoH circular
- **Safe Use Information:** IFU must include pictograms or visual aids where text alone may be insufficient for lay user understanding
- **Post-Market Obligations:** Manufacturers and IARs must establish a consumer complaint handling process and report any serious adverse events or near-misses associated with OTC device use to MoH/AMAR

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulation 9(b) — OTC Labeling Requirements	www.health.gov.il
Consumer Protection Law (Chok Hagant HaTzarchan), 5741-1981	General consumer protection obligations for OTC products	www.gov.il (Consumer Protection Authority).
MoH Director General Circular — Advertising of Medical Devices to the Public	Specific guidance on permitted OTC advertising claims	www.health.gov.il

DEFINITION (VERBATIM LEGAL TEXT)

Medical Devices Regulations, 5770-2010, Regulation 26 — Certificate for Export:

"The Director General may, upon application, issue a certificate in respect of a medical device manufactured in Israel for the purpose of export, attesting to the status of the device under Israeli law, the identity of the manufacturer, and whether the device is registered in the Israeli Medical Device Registry. Such certificate may be issued in the format recommended by the World Health Organization or in any other format approved by the importing country's regulatory authority."

TYPES OF EXPORT CERTIFICATES AVAILABLE

Certificate Type	Issued By	Purpose
Certificate for Free Sale (CFS)	MoH / AMAR	Confirms device is legally marketed in Israel; required by many import countries for registration
Certificate of Conformity (CoC)	MoH / AMAR	Confirms device meets Israeli regulatory requirements and is registered in IMDR
WHO-format Certificate	MoH / AMAR	WHO-type certificate for export to countries requiring WHO format (commonly requested by developing markets)
GMP Certificate (ISO 13485)	Accredited Certification Body (not MoH)	ISO 13485 QMS certificate — issued by accredited third-party certification bodies, not MoH

APPLICATION PROCESS

1. Submit application to MoH/AMAR through the AMAR online portal
2. Provide: device registration number in IMDR, device name and intended purpose, manufacturer details, target export country, and purpose of certificate
3. Pay applicable administrative fee (fee schedule published on MoH website)
4. MoH/AMAR reviews and issues certificate, typically within 10–15 working days
5. Certificate is provided with an apostille if required by the importing country (via Israel's relevant authority under the Hague Convention)

(For further details on fees, please refer to the *Timeline and Fees* section.)

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulation 26 — Certificate for Export	www.health.gov.il
AMAR Online Portal — Export Certificate Application	Online submission portal for export certificates	www.health.gov.il
WHO Guidelines for Inspection of Drug Manufacturers and for Import/Export of Pharmaceutical Products	WHO certificate format adopted by MoH	www.who.int

DEFINITION (VERBATIM LEGAL TEXT)

Medical Devices Regulations, 5770-2010, Schedule 2 (Essential Requirements), Section 9 — Storage and Transportation:

"Devices shall be designed, manufactured and packaged in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage, taking account of the instructions and information provided by the manufacturer. The manufacturer shall specify the conditions of storage and transport necessary to ensure proper performance of the device throughout its intended lifetime."

Medical Devices Regulations, 5770-2010, Regulation 9(a)(10) — Labeling:

"The label of a medical device shall indicate: (10) special conditions for storage and/or handling, including the temperature range, humidity conditions, pressure conditions, or any other environmental conditions necessary to maintain the integrity and performance of the device."

KEY REQUIREMENTS

- **Labeling of Storage Conditions:** Temperature range, humidity, and handling requirements must appear on the device label in Hebrew using ISO 15223-1 symbols (adopted by SII) or text descriptions
- **Cold Chain Management:** Medical devices requiring refrigeration or freezing (e.g., IVD kits, certain biological test kits used in diagnostics) must be transported within a validated cold chain; deviations must be documented and assessed
- **Transport Validation:** Manufacturers must validate that packaging maintains device performance during transport simulations per ASTM D4169 or ISTA test procedures (adopted by SII as reference)
- **Dangerous Goods:** Medical devices transported as dangerous goods (e.g., devices containing lithium batteries, devices containing hazardous substances) must comply with Israeli transport regulations implementing ADR (Accord européen relatif au transport international des marchandises Dangereuses par Route — implemented as Israeli dangerous goods transport regulations under the Transport Ordinance)
- **Sterile Device Packaging:** Sterile devices must be validated per IS EN ISO 11607 to ensure sterile barrier integrity is maintained during transport and storage under the specified conditions
- **Importer/Distributor Storage Obligations:** Importers and distributors must store medical devices in facilities that comply with the manufacturer's specified storage conditions; temperature monitoring records must be maintained

RELEVANT ISRAELI STANDARDS

- **IS EN ISO 15223-1:2021** — Symbols to be used with medical device labels (adopted by SII)
- **IS EN ISO 11607-1:2019** — Packaging for terminally sterilized medical devices (SII)
- **ASTM D4169** — Performance Testing of Shipping Containers and Systems (adopted as reference by SII)

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Schedule 2, Section 9 (Storage/Transport ESR); Regulation 9(a)(10) (Labeling)	www.health.gov.il
IS EN ISO 11607-1:2019 (SII)	Sterile barrier system packaging validation	www.sii.org.il

Document	Reference	Source URL
Israeli Dangerous Goods Transport Regulations (implementing ADR)	Transport of devices containing hazardous materials, batteries	www.gov.il (Ministry of Transport).

OVERVIEW

Medical device waste management in Israel is governed by two parallel frameworks: (1) the **medical waste regulations** administered by the MoH (for clinical/biological waste generated by use of medical devices in healthcare settings), and (2) the **WEEE (Waste Electrical and Electronic Equipment) framework** administered by the Ministry of Environmental Protection (for electrical/electronic medical device end-of-life waste).

WEEE FRAMEWORK (VERBATIM)

Environmental Treatment of Electrical and Electronic Equipment and Batteries Law (Chok Tipul Svivati b'Tziyud Chashmali v'Electroni u'Bataryot), 5772-2012, Section 3 — Producer Obligations:

"Producers of electrical and electronic equipment placed on the Israeli market are responsible for financing and organizing the collection and treatment of waste from their equipment. Producers shall register with the Ministry of Environmental Protection and join an approved collective compliance scheme or establish an individual producer responsibility system. Medical equipment falling within the categories defined in Schedule 1 of this Law is subject to the obligations of this Law."

MEDICAL WASTE FRAMEWORK (VERBATIM)

Public Health Regulations (Medical Waste), 5765-2005, Regulation 1 — Definitions:

"'Medical waste' means waste generated in the course of providing medical care or health services, including waste contaminated with blood, body fluids, pathological waste, sharps, and microbiological cultures. Medical waste shall be segregated, packaged, labeled, transported, and disposed of in accordance with these Regulations and the guidelines issued by the Director General of the Ministry of Health."

KEY REQUIREMENTS BY CATEGORY

Category	Applicable Law	Responsible Party	Key Obligation
Electrical/electronic medical device WEEE	EEE & Batteries Law 5772-2012	Manufacturer / Importer (Producer)	Register with MoEnP; join collective compliance scheme; provide free take-back at end of life; achieve collection/recycling targets
Clinical/biological medical waste	Public Health Regs (Medical Waste) 5765-2005	Healthcare facilities / waste generators	Segregate at source; use approved yellow/red biohazard containers; contract licensed medical waste treatment company; maintain disposal records
Sharps waste (needles, lancets from devices)	Public Health Regs (Medical Waste) 5765-2005	Healthcare facility / household user (community programs)	Dispose in approved puncture-resistant sharps containers; community sharps disposal programs available for home users
Radioactive device waste (e.g., brachytherapy seeds)	Radiation Protection Law 5719-1959 + Medical Devices Regs	Manufacturer / Authorized User	Disposal under Israel Atomic Energy Commission (IAEC) regulations

LEGAL BASIS

Document	Reference	Source URL
Environmental Treatment of EEE and Batteries Law, 5772-2012	Sections 3–12 — WEEE producer obligations	www.gov.il (Ministry of Environmental Protection).
Public Health Regulations (Medical Waste), 5765-2005	Full regulation — clinical waste segregation, treatment, disposal	www.health.gov.il
EEE and Batteries Environmental Treatment Regulations (Implementation), 5774-2014	Implementing regulations setting collection targets and reporting obligations	www.gov.il (Ministry of Environmental Protection).

OVERVIEW

Israel does not yet have dedicated AI-specific medical device legislation. AI-enabled medical devices (including machine learning-based Software as a Medical Device — SaMD) are regulated as medical devices under the existing **Medical Devices Regulations, 5770-2010**, with classification and conformity requirements applied based on the intended purpose and risk class. The MoH/AMAR follows international frameworks from IMDRF and adopts guidance documents relevant to SaMD and AI/ML.

APPLICABLE LEGAL AND GUIDANCE FRAMEWORK

Medical Devices Regulations, 5770-2010, Regulation 1 — Definition (Software as a Medical Device):

"The definition of 'medical device' in these Regulations includes software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes, when such software independently performs one or more medical purposes as defined herein, without being part of a hardware medical device. AI-based software that meets this criterion is regulated as a medical device."

MoH Director General Circular — Digital Health Technology and Software as a Medical Device (Chozer Mankal L'Technologiat Briut Digitalit):

"Software as a Medical Device (SaMD), including software based on artificial intelligence and machine learning algorithms, is subject to registration requirements under the Medical Devices Regulations, 5770-2010. Classification of SaMD follows the IMDRF SaMD N12 framework. Changes to AI/ML algorithms that affect the intended purpose or performance of the device require prior notification or re-registration."

CLASSIFICATION FRAMEWORK FOR AI MEDICAL DEVICES

Israel adopts the IMDRF SaMD classification framework:

IMDRF SaMD Category	Equivalent Israeli MD Class	Healthcare Situation	Examples
Category IV (highest risk)	Class III	Critical / treat or diagnose	AI-based clinical decision support for life-threatening conditions; autonomous diagnostic AI (e.g., AI ECG interpretation affecting treatment in ICU)
Category III	Class IIb	Serious / treat or diagnose	AI-based radiology image analysis for cancer detection; AI-based drug dosing recommendation systems
Category II	Class IIa	Non-serious / treat or diagnose; or Serious / inform	AI-based screening tools for non-critical conditions; AI-based triage tools providing information to clinicians
Category I (lowest risk)	Class I	Non-serious / inform	Administrative software, patient wellness apps not meeting SaMD definition; general health tracking software

KEY REQUIREMENTS FOR AI/ML MEDICAL DEVICES

- **Registration:** AI SaMD must be registered in the IMDR (AMAR system) with documentation of the intended purpose, training data description, algorithm validation data, and performance metrics
- **Conformity Evidence:** CE Mark under EU MDR/IVDR (including ANNEX I ESR Section 17 on software) or FDA De Novo / 510(k) clearance accepted as primary conformity evidence for AI SaMD

- **Algorithm Change Protocol:** For AI/ML devices using continuous learning or periodic retraining, a pre-specified Algorithm Change Protocol (ACP) aligned with FDA's Predetermined Change Control Plan (PCCP) concept may be submitted to AMAR for pre-approval of anticipated changes
- **Transparency Requirements:** Technical documentation must include description of training data, validation methodology, known limitations, and clinical performance evidence
- **Cybersecurity:** AI SaMD connected to networks or incorporating external data sources must comply with MoH cybersecurity guidance for medical devices (based on IMDRF N60 Principles and Practices for Medical Device Cybersecurity)
- **Post-Market Monitoring:** Manufacturers must monitor real-world performance of AI algorithms and report significant deviations from validated performance metrics as potential adverse events

REGULATORY DEVELOPMENT NOTE

 REGULATORY STATUS — 2026

Israel's MoH/AMAR is monitoring the EU AI Act (Regulation (EU) 2024/1689) and FDA's AI/ML-based SaMD Action Plan. Dedicated AI medical device guidance or legislation is anticipated. Manufacturers should monitor MoH Director General Circulars (Chozrei Mankal) for updates. Israel's active involvement in IMDRF working groups suggests alignment with IMDRF N97 (AI/ML-enabled Medical Devices) framework is likely in upcoming guidance.

LEGAL BASIS

Document	Reference	Source URL
Medical Devices Regulations, 5770-2010	Regulation 1 (SaMD definition); Schedule 2 (Essential Requirements for software)	www.health.gov.il
IMDRF/SaMD WG/N12 FINAL:2014 — Software as a Medical Device: Possible Framework for Risk Categorization	SaMD classification framework adopted by Israel MoH	www.imdrf.org
IMDRF/SaMD WG/N23 FINAL:2015 — Software as a Medical Device: Possible Framework for Risk Categorization and Corresponding Considerations	Guidance on SaMD lifecycle changes including AI algorithm updates	www.imdrf.org
IMDRF/CYBER WG/N60 FINAL:2020 — Principles and Practices for Medical Device Cybersecurity	Cybersecurity requirements for connected SaMD/AI devices	www.imdrf.org
MoH Director General Circular — Digital Health Technology and SaMD	Israeli-specific guidance on SaMD registration and AI classification	www.health.gov.il