



Reliance Pathway Report

Global Medical Device Regulatory Analysis — 133 Markets
RegDesk Data Intelligence | July 2025

Purpose: This report analyzes whether a regulatory reliance pathway exists for medical device approvals in each market RegDesk serves, the nature of that pathway, and whether a Free Sale Certificate (FSC) or Certificate of Good Standing (CGF) is required as part of the submission.

133

Markets Analyzed

Reliance Pathway Status (Q1)

- ☒ **YES** — Formal pathway exists: **88** markets
- ☒ **PARTIAL** — Developing / de facto reliance: **35** markets
- ☒ **NO** — Independent review only: **1** markets
- ☐ **UNKNOWN** — Insufficient data: **9** markets

FSC / Certificate of Good Standing Requirement (Q3)

52

Required (YES)

35

Not Required (NO)

28

Sometimes

18

Unknown

Key Findings:

- **88** markets (66%) have a formal reliance pathway — offering streamlined approval for devices already cleared by reference authorities (FDA, CE, TGA, Health Canada).
- **35** markets (26%) have partial or developing reliance frameworks, often accepting foreign approvals as supporting evidence.
- **80** markets require or sometimes require an FSC/CGF as part of the reliance submission.
- EU/EEA markets (27 EU + Iceland, Liechtenstein, Norway) and Switzerland operate under CE marking — no FSC needed.
- Conflict-affected or fragile states (Afghanistan, Yemen, Syria, etc.) have no functional regulatory capacity.



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Afghanistan	UNKNOWN	Afghanistan has very limited medical device regulatory infrastructure. There is no known formal reliance pathway. Regulatory oversight falls loosely under the Ministry of Public Health, but enforce...	UNKNOWN
Albania	PARTIAL	Albania is an EU candidate country and has been aligning its regulatory framework with EU MDR. CE-marked devices are accepted as a reference, though a formal full reliance pathway is not yet fully ...	SOMETIMES
Algeria	PARTIAL	Algeria's Ministry of Health regulates medical devices through the National Agency for Pharmaceutical Products (ANPP). CE marking and approvals from recognized authorities are taken into account, b...	YES
Argentina	YES	ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) operates a formal reliance pathway that accepts approvals from reference regulatory authorities including FDA, EMA/CE,...	YES
Armenia	YES	Armenia is a member of the Eurasian Economic Union (EAEU) and implements the EAEU Technical Regulation on medical devices (TR EAEU 017/2011). Devices registered in another EAEU member state (Russia...	SOMETIMES
Australia	YES	The Therapeutic Goods Administration (TGA) operates a formal reliance pathway under the ARTG (Australian Register of Therapeutic Goods). TGA accepts CE marking, FDA clearance/approval, and approval...	SOMETIMES
Austria	YES	Austria is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access without a separate national registration. No country-level reliance pathwa...	NO
Azerbaijan	PARTIAL	Azerbaijan has a developing regulatory framework under the Ministry of Health. CE marking and Russian regulatory approvals are often used as de facto references during import control, though there ...	UNKNOWN
Bahrain	YES	Bahrain's National Health Regulatory Authority (NHRA) follows GCC (Gulf Cooperation Council) mutual recognition and relies on approvals from a reference country list including FDA, CE, TGA, Health ...	YES
Bangladesh	PARTIAL	The Directorate General of Drug Administration (DGDA) regulates medical devices in Bangladesh under the Drug Act 1940 (with amendments). A formal, codified reliance pathway does not exist, but CE-m...	SOMETIMES
Belarus	YES	Belarus is a member of the EAEU and implements TR EAEU 017/2011 for medical devices. Devices registered in any EAEU member state can benefit from mutual recognition procedures. Belarus also has bil...	SOMETIMES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Belgium	YES	Belgium is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking provides direct market access throughout the EU single market. No separate Belgian national registration ...	NO
Belize	UNKNOWN	Belize has no formal medical device-specific regulation. The Ministry of Health oversees imported health products, and import permits may require documentation from the country of origin, but there...	UNKNOWN
Benin	UNKNOWN	Benin lacks a dedicated medical device regulatory framework. The Ministry of Health manages imports, and some reliance on WHO prequalification or ECOWAS-level guidance may apply informally. No form...	UNKNOWN
Bolivia	PARTIAL	AGEMED (Agencia Estatal de Medicamentos y Tecnologías en Salud) regulates medical devices in Bolivia. Approvals from reference authorities such as FDA and CE are taken as supporting evidence during...	YES
Bosnia and Herzegovina	PARTIAL	The Agency for Medicinal Products and Medical Devices (ALMBIH) regulates medical devices in Bosnia and Herzegovina. The country is an EU candidate and has partially aligned its regulations with EU ...	SOMETIMES
Botswana	YES	Botswana Medicines Regulatory Authority (BOMRA) has established a reliance framework that accepts approvals from WHO-listed stringent regulatory authorities (SRAs) including FDA, EMA/CE, TGA, and H...	YES
Brazil	YES	ANVISA operates a formal reliance pathway — the ISED (Equiparação com Autoridade Regulatória Estrangeira) pathway — for medical devices approved by reference authorities including FDA, EMA, CE (Not...	YES
Bulgaria	YES	Bulgaria is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access in Bulgaria as part of the EU single market. No separate Bulgarian nation...	NO
Cambodia	PARTIAL	The Department of Drugs and Food (DDF) under Cambodia's Ministry of Health regulates medical devices. A formal reliance pathway is not fully codified, but CE-marked and FDA-cleared devices are trea...	SOMETIMES
Cameroon	UNKNOWN	Cameroon's Ministry of Public Health oversees medical device imports, but a dedicated medical device regulatory law or formal reliance pathway does not exist. Import permits may reference documenta...	UNKNOWN
Canada	YES	Health Canada operates a recognition/reliance pathway for medical devices, accepting data and decisions from recognized foreign regulatory authorities (FDA, EMA, TGA, UK MHRA, Japan PMDA) to suppor...	SOMETIMES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Chile	YES	The Institute of Public Health (ISP) under Chile's Ministry of Health regulates medical devices. Chile has a formal reliance mechanism that accepts prior approvals from reference authorities includ...	YES
China	PARTIAL	China's NMPA (National Medical Products Administration, formerly CFDA) primarily operates an independent review system for medical devices. However, for innovative devices, NMPA has introduced expe...	NO
Colombia	YES	INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos) has a formal reliance pathway under Decree 4725/2005 that accepts approvals from reference regulatory authorities (FDA, CE, Hea...	YES
Costa Rica	YES	The CONIS (Consejo Nacional para Investigaciones en Salud) and MINSA (Ministry of Health) regulate medical devices in Costa Rica. A reliance pathway exists that accepts FDA and CE approvals as the ...	YES
Croatia	YES	Croatia is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking provides direct market access across the EU including Croatia. No separate national Croatian registration...	NO
Cuba	PARTIAL	CECMED (Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos) regulates medical devices in Cuba. Cuba largely conducts independent technical review and does not have a for...	UNKNOWN
Cyprus	YES	Cyprus is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access in Cyprus as part of the EU single market. No separate Cypriot national reg...	NO
Czech Republic	YES	The Czech Republic is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking provides direct market access. The State Institute for Drug Control (SUKL) oversees vigilance ...	NO
Côte d'Ivoire	UNKNOWN	Côte d'Ivoire lacks a dedicated medical device regulatory framework. The Ministry of Health manages healthcare product imports under general pharmaceutical regulations. No formal reliance pathway r...	UNKNOWN
Denmark	YES	Denmark is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. The Danish Medicines Agency (DKMA) oversees vigilance but does not requir...	NO
Dominican Republic	PARTIAL	DIGEMAPS (Dirección General de Medicamentos, Alimentos y Productos Sanitarios) under the Ministry of Public Health regulates medical devices. Some reliance on FDA and CE approvals exists, but a for...	YES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Ecuador	YES	ARCSA (Agencia Nacional de Regulación, Control y Vigilancia Sanitaria) regulates medical devices in Ecuador. A reliance pathway exists that accepts prior approvals from FDA, CE, Health Canada, and ...	YES
Egypt	YES	EGMED (Egyptian Medical Devices Committee under CAPA — Central Administration of Pharmaceutical Affairs) regulates medical devices. Egypt has a formal reliance pathway that accepts CE marking and F...	YES
El Salvador	PARTIAL	CSSP (Consejo Superior de Salud Pública) and the Ministry of Health regulate medical devices in El Salvador. Some reliance on FDA and CE approvals exists as supporting documentation, but a full cod...	YES
Estonia	YES	Estonia is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU including Estonia. No separate Estonian registration is requ...	NO
Eswatini	YES	The Eswatini Food and Drugs Authority (SFDA) has established a reliance framework that references WHO-listed SRA approvals (FDA, EMA/CE, TGA, Health Canada) to support medical device registration. ...	YES
Ethiopia	YES	The Ethiopian Food and Drug Authority (EFDA) has implemented a reliance pathway under its medical devices regulatory framework that accepts approvals from WHO-listed SRAs (FDA, EMA/CE, TGA, Health ...	YES
Finland	YES	Finland is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. Fimea (Finnish Medicines Agency) oversees vigilance but does not require ...	NO
France	YES	France is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access throughout the EU. ANSM (Agence Nationale de Sécurité du Médicament) overse...	NO
Georgia	PARTIAL	Georgia has been progressively aligning its regulatory framework with EU standards under the EU-Georgia Association Agreement. CE marking is accepted as a key reference for medical device registrat...	SOMETIMES
Germany	YES	Germany is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking provides direct market access across the EU. BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) ...	NO
Ghana	YES	The Food and Drugs Authority (FDA) of Ghana has a medical device registration framework that incorporates reliance provisions. Approvals from WHO-listed SRAs (FDA US, EMA/CE, TGA, Health Canada) ar...	YES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Greece	YES	Greece is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. EOF (National Organization for Medicines) manages vigilance but CE-marked ...	NO
Guatemala	PARTIAL	The DRCA (Departamento de Regulación y Control de Alimentos) under Guatemala's Ministry of Health regulates medical devices. Some reliance on FDA and CE approvals exists as supporting documentation...	YES
Guyana	PARTIAL	The Food and Drug Department of Guyana manages healthcare product imports under the Food and Drug Act. A formal medical device-specific reliance pathway does not exist, but CE and FDA documentation...	UNKNOWN
Honduras	YES	ARSA (Agencia de Regulación Sanitaria) of Honduras has a reliance-based registration pathway that accepts approvals from reference regulatory authorities including FDA, CE, Health Canada, and PAHO-...	YES
Hong Kong	YES	The Medical Device Administrative Control System (MDACS) under Hong Kong's Department of Health operates a formal reliance pathway. Devices approved by recognized reference authorities (FDA, CE, TG...	YES
Hungary	YES	Hungary is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU including Hungary. No separate Hungarian national registrati...	NO
Iceland	YES	Iceland is an EEA (European Economic Area) member and implements EU MDR through the EEA Agreement. CE marking grants full market access in Iceland as in EU member states. The Icelandic Medicines Ag...	NO
India	YES	CDSCO (Central Drugs Standard Control Organisation) has reliance provisions under the Medical Devices Rules 2017 (MDR 2017, amended 2020). Class A and B devices manufactured by SRA-approved manufac...	YES
Indonesia	YES	BPOM (Badan Pengawas Obat dan Makanan) regulates medical devices in Indonesia. A formal reliance pathway exists that accepts approvals from reference authorities (FDA, CE, TGA, Health Canada) as th...	YES
Iraq	PARTIAL	The Ministry of Health (KIMADIA) oversees medical device imports in Iraq. A formal written reliance pathway does not exist, but CE marking and FDA clearance documentation are required as part of th...	SOMETIMES
Ireland	YES	Ireland is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants direct market access. The Health Products Regulatory Authority (HPRA) oversees vigilance; no separ...	NO



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Israel	YES	The Medical Devices Division (AMAR) of Israel's Ministry of Health operates a formal reliance pathway. Devices approved by FDA (510(k)/PMA) or CE-marked by a Notified Body qualify for an abridged r...	YES
Italy	YES	Italy is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU. AIFA/Ministero della Salute manages vigilance, but CE-marked ...	NO
Jamaica	PARTIAL	The Ministry of Health and Wellness of Jamaica oversees medical device imports under the Food and Drugs Act. A formal, dedicated medical device regulatory framework with a codified reliance pathway...	UNKNOWN
Japan	PARTIAL	PMDA (Pharmaceuticals and Medical Devices Agency) and MHLW conduct medical device review in Japan. Japan largely requires an independent review process (Shonin/Ninsho), but some provisions exist to...	NO
Jordan	YES	The Jordan Food and Drug Administration (JFDA) has a formal reliance pathway for medical devices. Approvals from reference regulatory authorities (FDA, CE, TGA, Health Canada, PMDA) are accepted as...	YES
Kazakhstan	YES	Kazakhstan is an EAEU member and implements TR EAEU 017/2011 for medical devices. Devices registered elsewhere in the EAEU (Russia, Belarus, Armenia, Kyrgyzstan) benefit from a mutual recognition/u...	SOMETIMES
Kenya	YES	The Pharmacy and Poisons Board (PPB) of Kenya regulates medical devices and has a reliance framework that accepts approvals from WHO-listed SRAs (FDA, EMA/CE, TGA, Health Canada) as the primary ref...	YES
Kosovo	PARTIAL	Kosovo's Agency for Medicinal Products and Medical Devices (AKBMPM) is in the process of aligning with EU MDR as Kosovo pursues EU integration. CE marking is accepted as the primary reference, thou...	SOMETIMES
Kuwait	YES	Kuwait's Ministry of Health (Department of Pharmaceutical Affairs) follows GCC harmonized regulations and the GCC reference country list approach. Devices approved by FDA, CE, TGA, Health Canada, o...	YES
Kyrgyzstan	YES	Kyrgyzstan is an EAEU member and implements TR EAEU 017/2011 for medical devices. Devices registered in any other EAEU member state benefit from the EAEU mutual recognition/unified registration pro...	SOMETIMES
Laos	PARTIAL	The Food and Drug Department (FDD) under Laos's Ministry of Health regulates medical devices. A formal reliance pathway is not fully established, but CE and FDA approvals are referenced as supporti...	SOMETIMES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Latvia	YES	Latvia is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU including Latvia. No separate Latvian national registration i...	NO
Lebanon	YES	The Lebanese Ministry of Public Health (MOPH) has a medical device registration system that operates on a de facto reliance basis. CE marking and FDA clearance/approval are required as primary evid...	YES
Liechtenstein	YES	Liechtenstein is an EEA member and implements EU MDR through the EEA Agreement. CE marking provides full market access in Liechtenstein equivalent to EU member states. The Office of Health oversees...	NO
Lithuania	YES	Lithuania is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. VVKT (State Medicines Control Agency) oversees vigilance but CE-marked ...	NO
Luxembourg	YES	Luxembourg is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU. No separate Luxembourg national registration is required...	NO
Malaysia	YES	The Medical Device Authority (MDA) of Malaysia has a registration system under the Medical Device Act 2012. Malaysia has a formal registration process that accepts CE, FDA, TGA, and Health Canada a...	YES
Maldives	PARTIAL	The Maldives Food and Drug Authority (MFDA) oversees medical device imports. A dedicated formal reliance pathway for medical devices has not been fully established, but CE and FDA approvals are ref...	UNKNOWN
Malta	YES	Malta is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU. The Medicines Authority of Malta oversees vigilance; no separ...	NO
Mauritius	PARTIAL	The Pharmacy Board of Mauritius under the Ministry of Health regulates medical devices. A formal codified reliance pathway does not exist, but CE and FDA approval documentation is typically require...	SOMETIMES
Mexico	YES	COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios, now under CONASA) has a formal reliance pathway for medical devices under NOM-137 and COFEPRIS resolutions. Devices approved...	YES
Moldova	PARTIAL	Moldova's Agency for Medicines and Medical Devices (AMDM) has been aligning its regulatory framework with EU MDR as part of EU Association Agreement commitments. CE marking is accepted as a primary...	SOMETIMES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Mongolia	PARTIAL	Mongolia's Ministry of Health and relevant regulatory departments oversee medical device imports. A formal written reliance pathway does not exist, but CE and FDA documentation is used to support i...	UNKNOWN
Montenegro	PARTIAL	Montenegro is an EU candidate country and its Agency for Medicines and Medical Devices (CALIMS) has been aligning with EU MDR. CE marking is accepted as the primary reference, though full formal im...	SOMETIMES
Morocco	PARTIAL	Morocco's Ministry of Health, through its Direction du Médicament et de la Pharmacie, oversees medical device registration. CE marking and FDA approval are referenced in the registration dossier an...	SOMETIMES
Myanmar	PARTIAL	The Food and Drug Administration (FDA) of Myanmar oversees medical device registration. A formal reliance pathway is not fully codified, but CE and FDA approvals are referenced as supporting eviden...	SOMETIMES
Namibia	YES	The Namibia Medicines Regulatory Council (NMRC, now restructured under NAMRA) has a reliance framework that accepts approvals from WHO-listed SRAs for medical device registration. Devices approved ...	YES
Netherlands	YES	The Netherlands is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. CIBG/IGJ (Healthcare and Youth Inspectorate) oversees vigilance; ...	NO
New Zealand	YES	Medsafe (New Zealand's Medicines and Medical Devices Safety Authority) has a formal reliance pathway for medical devices. Devices approved by TGA, FDA, CE (via a Notified Body), Health Canada, or P...	SOMETIMES
Nicaragua	PARTIAL	MINSa (Ministerio de Salud) of Nicaragua manages medical device registration. FDA and CE approvals are used as reference documentation for registration, and MINSa formally accepts these as part of ...	YES
Nigeria	YES	NAFDAC (National Agency for Food and Drug Administration and Control) has a formal medical device registration system with reliance provisions. Approvals from WHO-listed SRAs (FDA, EMA/CE, TGA, Hea...	YES
North Macedonia	PARTIAL	North Macedonia's Agency for Medicines and Medical Devices (MALMED) is aligning with EU MDR as the country pursues EU membership. CE marking is accepted as the primary reference for device registra...	SOMETIMES
Norway	YES	Norway is an EEA member and implements EU MDR through the EEA Agreement. CE marking provides full market access in Norway, equivalent to EU member states. The Norwegian Medicines Agency (NoMA/NOMA)...	NO



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Oman	YES	Oman's Ministry of Health follows the GCC harmonized regulatory framework and the GCC reference country list. Devices approved by FDA, CE, TGA, Health Canada, or PMDA qualify for expedited registra...	YES
Pakistan	YES	DRAP (Drug Regulatory Authority of Pakistan) has reliance provisions under the DRAP Act 2012 and associated regulations. WHO prequalification and approvals from reference SRAs (FDA, EMA/CE, TGA, He...	YES
Palestine	PARTIAL	The Palestinian Ministry of Health has limited regulatory capacity for medical devices. Registration processes informally reference CE and FDA approvals for product import authorization, but no for...	UNKNOWN
Panama	YES	MINSA (Ministerio de Salud) and DNFD (Dirección Nacional de Farmacia y Drogas) of Panama operate a registration system that accepts FDA and CE approvals as the primary reference for device registra...	YES
Paraguay	YES	DINAVISA (Dirección Nacional de Vigilancia Sanitaria) under Paraguay's Ministry of Public Health regulates medical devices. Reliance provisions exist that accept approvals from reference authoritie...	YES
Peru	YES	DIGEMID (Dirección General de Medicamentos, Insumos y Drogas) of Peru has a formal reliance pathway for medical devices. Approvals from reference regulatory authorities (FDA, CE, Health Canada, TGA...	YES
Philippines	YES	The FDA of the Philippines has a formal reliance pathway under its medical device registration regulations. Class A and B (lower risk) devices from ASEAN manufacturers, and devices approved by refe...	YES
Poland	YES	Poland is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU. URPL (Office for Registration of Medicinal Products, Medical...	NO
Portugal	YES	Portugal is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. INFARMED (National Authority of Medicines and Health Products) oversees ...	NO
Puerto Rico	YES	Puerto Rico is a U.S. territory and is fully regulated under U.S. FDA regulations for medical devices (21 CFR). All FDA clearance/approval pathways (510(k), PMA, De Novo) apply directly without any...	NO
Qatar	YES	Qatar's Ministry of Public Health (MOPH) follows GCC harmonized regulations and the GCC reference country list approach. Devices approved by FDA, CE, TGA, Health Canada, or PMDA qualify for expedit...	YES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Republic of Serbia	YES	ALIMS (Medicines and Medical Devices Agency of Serbia) has a formal reliance pathway that accepts CE marking and FDA approvals as the primary basis for medical device registration. As an EU candida...	SOMETIMES
Romania	YES	Romania is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU. ANMDM (National Agency for Medicines and Medical Devices) o...	NO
Russia	PARTIAL	Roszdravnadzor regulates medical devices in Russia under the Federal Law on the Basics of Health Protection. Russia implements EAEU technical regulations (TR EAEU 017/2011), which provides mutual r...	SOMETIMES
Rwanda	YES	Rwanda's FDA (Rwanda Food and Drugs Authority) has implemented a reliance framework aligned with WHO's collaborative registration procedure. Devices approved by WHO-listed SRAs (FDA, EMA/CE, TGA, H...	YES
Saudi Arabia	YES	The Saudi Food and Drug Authority (SFDA) has one of the most developed reliance pathways in the region. SFDA accepts approvals from a reference country list (FDA, CE, TGA, Health Canada, PMDA) as t...	YES
Senegal	UNKNOWN	Senegal's regulatory framework for medical devices is very limited, primarily managed under the Directorate of Pharmacy and Medicine. No formal reliance pathway referencing international SRA approv...	UNKNOWN
Singapore	YES	The Health Sciences Authority (HSA) of Singapore has a formal and well-developed reliance pathway for medical devices. Devices approved by recognized reference regulatory authorities (FDA, CE via N...	YES
Slovakia	YES	Slovakia is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU. ŠÚKL (State Institute for Drug Control) oversees vigilance...	NO
Slovenia	YES	Slovenia is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. JAZMP (Agency for Medicinal Products and Medical Devices) oversees vigil...	NO
South Africa	YES	SAHPRA (South African Health Products Regulatory Authority) has a formal reliance pathway for medical devices established under its Medical Devices and IVDs Regulations. SAHPRA accepts approvals fr...	YES
South Korea	PARTIAL	MFDS (Ministry of Food and Drug Safety) of South Korea primarily conducts independent technical review for medical device approval. Some provisions exist to accept foreign approval data (particular...	SOMETIMES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Spain	YES	Spain is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access across the EU. AEMPS (Agencia Española de Medicamentos y Productos Sanitario...	NO
Sri Lanka	YES	The National Medicines Regulatory Authority (NMRA) of Sri Lanka has reliance provisions for medical device registration. WHO prequalification and approvals from reference SRAs (FDA, EMA/CE, TGA, He...	YES
Sudan	PARTIAL	Sudan's Federal Ministry of Health, through the Directorate General of Pharmacy, oversees medical device imports. CE and FDA approvals are referenced informally as supporting documentation during i...	UNKNOWN
Suriname	PARTIAL	Suriname's Ministry of Health manages healthcare product imports under general pharmaceutical regulations. A dedicated medical device regulatory framework with a formal reliance pathway does not ex...	UNKNOWN
Sweden	YES	Sweden is an EU member state and fully implements EU MDR (Regulation 2017/745). CE marking grants automatic market access. MPA (Medical Products Agency / Läkemedelsverket) oversees vigilance and so...	NO
Switzerland	YES	Swissmedic regulates medical devices in Switzerland. Under the Swiss-EU bilateral agreements (MRA), Switzerland has aligned its Medical Devices Act (MedDO) with EU MDR. CE-marked devices by Notifie...	NO
Syria	UNKNOWN	Syria's regulatory capacity for medical devices has been severely impacted. The Ministry of Health nominally oversees device imports, and CE marking is referenced informally for import authorizatio...	UNKNOWN
Taiwan	YES	Taiwan FDA (TFDA) has an expedited and reliance-based review pathway for medical devices. Devices with FDA 510(k)/PMA clearance or CE marking can apply for an abbreviated technical file review in T...	YES
Tanzania	YES	TMDA (Tanzania Medicines and Medical Devices Authority) has established a reliance framework that accepts approvals from WHO-listed SRAs (FDA, EMA/CE, TGA, Health Canada) for medical device registr...	YES
Thailand	YES	The FDA of Thailand (Thai FDA / TCFD) operates a reliance-based registration pathway for medical devices. Devices approved by reference authorities (FDA US, CE, TGA, Health Canada, PMDA) can be reg...	YES
Tunisia	PARTIAL	Tunisia's DHMPE (Direction de la Pharmacie et du Médicament) under the Ministry of Health manages medical device registrations. CE marking and FDA approvals are required as part of the registration...	YES



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Turkey	YES	TITCK (Türkiye İlaç ve Tıbbi Cihaz Kurumu — Turkish Medicines and Medical Devices Agency) has a formal reliance pathway under Turkish Medical Device Regulation (TTIYK), which is aligned with EU MDR...	SOMETIMES
Turkmenistan	UNKNOWN	Turkmenistan has a very limited and opaque regulatory framework for medical devices, managed under the Ministry of Health. No formal reliance pathway referencing international SRA approvals has bee...	UNKNOWN
Uganda	YES	The National Drug Authority (NDA) of Uganda has a reliance framework that accepts WHO prequalification and approvals from recognized SRAs (FDA, EMA/CE, TGA, Health Canada) as the basis for expedite...	YES
Ukraine	YES	Ukraine's State Service of Ukraine on Medicines and Drugs Control (SMCU/DSLZ) regulates medical devices. Under the EU-Ukraine Association Agreement, Ukraine is aligning with EU MDR, and CE marking ...	SOMETIMES
United Arab Emirates	YES	The UAE has a multi-authority system: DOH (Abu Dhabi), DHA (Dubai), and the Federal MOH&P. All follow the GCC harmonized framework and the UAE's own device registration guidelines that formally rel...	YES
United Kingdom	YES	Post-Brexit, the UK MHRA has implemented the UKCA marking system for Great Britain (England, Scotland, Wales). MHRA has a formal reliance pathway: CE-marked devices (issued by EU Notified Bodies) w...	SOMETIMES
United States of America	NO	The FDA operates its own independent medical device review system (510(k), De Novo, PMA, EUA). While FDA does participate in IMDRF and may accept foreign clinical data under certain conditions, FDA...	NO
Uruguay	YES	MSP (Ministerio de Salud Pública) of Uruguay regulates medical devices. Reliance provisions exist that accept approvals from reference regulatory authorities (FDA, CE, ANVISA, Health Canada, TGA) a...	YES
Venezuela	PARTIAL	INHRR (Instituto Nacional de Higiene Rafael Rangel) regulates medical devices in Venezuela. Regulatory capacity has been limited in recent years. CE and FDA approvals are referenced in registration...	SOMETIMES
Vietnam	YES	The Drug Administration of Vietnam (DAV) under the Ministry of Health has reliance provisions for medical device registration. Devices approved by reference authorities (FDA, CE/EU Notified Body, T...	YES
Yemen	UNKNOWN	Yemen's regulatory capacity for medical devices has been severely impacted by the ongoing conflict. The Ministry of Public Health nominally oversees health product imports, and CE/FDA documentation...	UNKNOWN



Country	Reliance Pathway	Pathway Description	FSC/CGF Required
Zimbabwe	YES	MCAZ (Medicines Control Authority of Zimbabwe) regulates medical devices and has reliance provisions that accept approvals from WHO-listed SRAs (FDA, EMA/CE, TGA, Health Canada) as the basis for ex...	YES