

REGDESK DATA INTELLIGENCE

Reliance Pathway Global Report

146 Countries & Regional Groupings

Medical Device Regulatory Reliance Analysis — July 2026

58

Countries with
Full Pathway

59

Countries with
Partial Pathway

17

Countries with
No Pathway

Prepared by RegDesk Data Team — Confidential

Executive Summary

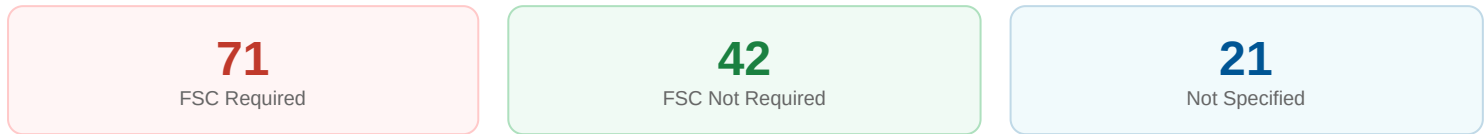
This report provides a comprehensive analysis of medical device **reliance pathways** across **146 markets** served by RegDesk, covering sovereign countries, territories, and regional regulatory groupings. A reliance pathway refers to a formal mechanism by which a national regulatory authority accepts or leverages a prior marketing authorization from a recognized reference authority (FDA, EMA, TGA, Health Canada, PMDA, etc.) to simplify or accelerate domestic device registration.



Key Findings

- EU/EEA bloc (30 markets):** All EU member states + Norway, Iceland, Liechtenstein rely on the CE marking framework under EU MDR/IVDR. No FSC required.
- GCC countries (6 markets):** Saudi Arabia, UAE, Kuwait, Qatar, Bahrain, and Oman have formal reliance on CE/FDA approvals. FSC is typically required.
- ASEAN bloc (10 markets):** Partial harmonization through the ASEAN Medical Device Directive (AMDD). FSC generally required.
- EAEU bloc (5 markets):** Russia, Kazakhstan, Belarus, Armenia, Kyrgyzstan — unified EAEU system. Partially reliant on reference approvals.
- Conflict/failed states (5 markets):** Afghanistan, Syria, Yemen, Sudan, and similar — no functional reliance pathway due to regulatory disruption.

FSC/CGF Requirement Overview



Country-by-Country Reliance Pathway Analysis (134 Countries)

Country	Pathway	Description	FSC Required
Afghanistan	NO	Afghanistan does not have a formal medical device regulatory framework or reliance pathway. The Ministry of Public Health oversees medicines but medical devices are largely unregulated with no formal ...	NOT SPECIFIED
Albania	YES	Albania as an EU candidate country aligns its medical device regulations with EU MDR/IVDR. The Albanian Drug and Medical Devices Agency (AMA) accepts CE-marked devices and relies on EU notified body d...	REQUIRED
Algeria	PARTIAL	Algeria's National Agency of Pharmaceutical Products (ANPP) requires local registration of medical devices. While there is no formal reliance pathway, a CE mark or FDA clearance/approval can support t...	REQUIRED
Argentina	YES	ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) has a formal reliance pathway that accepts approvals from FDA, EMA, Health Canada, TGA, and ANVISA to expedite local regi...	REQUIRED
Armenia	PARTIAL	Armenia is part of the Eurasian Economic Union (EAEU) and applies the unified EAEU medical device registration procedure. EAEU registration uses a common technical dossier but does not formally rely o...	REQUIRED
Australia	YES	The TGA has a formal Comparable Overseas Regulator (COR) reliance pathway that accepts prior approvals from FDA, EMA (EU Notified Bodies), Health Canada, PMDA, UK MHRA, and Singapore HSA to streamline...	NOT REQUIRED
Austria	YES	Austria is an EU Member State and applies EU MDR/IVDR directly. Device registration relies on CE marking issued by EU-recognized notified bodies; the national competent authority (BASG) does not condu...	NOT REQUIRED
Azerbaijan	PARTIAL	Azerbaijan's Ministry of Health requires registration of medical devices. CE marking or FDA clearance can support the registration dossier, but there is no formal reliance pathway. A Free Sale Certifi...	REQUIRED
Bahrain	YES	Bahrain's National Health Regulatory Authority (NHRA) accepts CE marking and FDA 510(k)/PMA approvals as basis for expedited medical device registration. As a GCC member, Bahrain follows the Gulf Coop...	REQUIRED
Bangladesh	PARTIAL	The Directorate General of Drug Administration (DGDA) in Bangladesh oversees medical device imports. While no formal reliance pathway exists, CE marking or FDA approval is typically required as suppor...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Belarus	PARTIAL	Belarus is part of the Eurasian Economic Union (EAEU) and follows the unified EAEU medical device registration system. The EAEU framework uses a common technical dossier approach but does not formally...	NOT SPECIFIED
Belgium	YES	Belgium is an EU Member State and fully applies EU MDR/IVDR. CE marking issued by EU-recognized notified bodies is required; the FAMHP (Federal Agency for Medicines and Health Products) does not condu...	NOT REQUIRED
Belize	NO	Belize does not have a specific medical device regulatory framework or formal reliance pathway. Medical device imports are generally managed through customs and import regulations without a dedicated ...	NOT SPECIFIED
Benin	NO	Benin does not have a dedicated medical device regulatory framework. The country relies on broader pharmaceutical regulations and WHO prequalification where applicable, but no formal reliance pathway ...	NOT SPECIFIED
Bolivia	PARTIAL	AGEMED (Agencia Estatal de Medicamentos y Tecnologías en Salud) in Bolivia requires registration of medical devices. CE marking or FDA clearance supports the application dossier, but no formal relianc...	REQUIRED
Bosnia and Herzegovina	YES	Bosnia and Herzegovina's Agency for Medicinal Products and Medical Devices (ALIMS) largely aligns with EU MDR/IVDR as part of its EU accession process. CE-marked devices are broadly accepted, with the...	REQUIRED
Botswana	PARTIAL	Botswana Medicines Regulatory Authority (BoMRA) was established in 2018 and is still developing its full medical device regulatory framework. BoMRA accepts WHO prequalification and major reference reg...	REQUIRED
Brazil	YES	ANVISA has a formal priority review/reliance pathway under RDC regulations that accepts prior approvals from recognized reference regulators including FDA, EMA, Health Canada, TGA, and Japan PMDA. Dev...	REQUIRED
Bulgaria	YES	Bulgaria is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the Bulgarian Drug Agency (BDA) does not require a...	NOT REQUIRED
Cambodia	PARTIAL	Cambodia's Department of Drug and Food (DDF) under the Ministry of Health oversees medical device registration. As an ASEAN member, Cambodia is part of AMDD harmonization efforts. CE marking or approv...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Cameroon	PARTIAL	Cameroon's Ministry of Public Health regulates medical devices but no formal reliance pathway exists. CE marking or WHO prequalification is typically referenced in registration submissions. The regula...	NOT SPECIFIED
Canada	PARTIAL	Health Canada participates in MDSAP (Medical Device Single Audit Program) and has bilateral information-sharing arrangements with FDA, TGA, and other IMDRF members. While there is no formal pathway th...	NOT REQUIRED
Chile	PARTIAL	Chile's ISP (Instituto de Salud Pública) / ANAMED requires medical device registration. FDA clearance/approval or CE marking is accepted as supporting evidence in the registration dossier and can faci...	REQUIRED
China	PARTIAL	NMPA (National Medical Products Administration) has a priority review pathway for innovative and urgently needed medical devices, and an expedited pathway for devices already approved in other jurisd...	NOT REQUIRED
Colombia	PARTIAL	INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos) accepts FDA, EMA, and other reference regulator approvals as supporting documentation and offers an expedited review process for d...	REQUIRED
Costa Rica	PARTIAL	Costa Rica's CCSS (Caja Costarricense de Seguro Social) and MINSA regulate medical device imports. FDA clearance or CE marking can support the import/registration process. No formal reliance pathway e...	REQUIRED
Croatia	YES	Croatia is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the Croatian Agency for Medicinal Products and Medi...	NOT REQUIRED
Cuba	NO	Cuba's CECMED (Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos) conducts independent national review of medical devices and does not have a formal reliance pathway. The ...	NOT SPECIFIED
Cyprus	YES	Cyprus is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization, with no additional national device registration requ...	NOT REQUIRED
Czech Republic	YES	Czech Republic is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the SÚKL (State Institute for Drug Control) ...	NOT REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Côte d'Ivoire	NO	Côte d'Ivoire does not have a dedicated medical device regulatory framework or formal reliance pathway. The regulatory framework for medical devices is minimal, with WAEMU (West African Economic and M...	NOT SPECIFIED
Denmark	YES	Denmark is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the DKMA (Danish Medicines Agency) does not conduct...	NOT REQUIRED
Dominican Republic	PARTIAL	DIGEMAPS (Dirección General de Medicamentos, Alimentos y Productos Sanitarios) requires registration of medical devices. FDA clearance/approval or CE marking is accepted as supporting evidence, and a ...	REQUIRED
Ecuador	PARTIAL	Ecuador's ARCSA (Agencia Nacional de Regulación, Control y Vigilancia Sanitaria) requires medical device registration. FDA clearance, CE marking, or approvals from recognized reference authorities can...	REQUIRED
Egypt	PARTIAL	Egypt's Egyptian Drug Authority (EDA) / Egyptian Medical Device Department requires registration of medical devices. CE marking and FDA clearance/approval are accepted as supporting documentation and ...	REQUIRED
El Salvador	PARTIAL	El Salvador's DNSM (Dirección Nacional de Medicamentos) oversees medical device regulation. FDA clearance or CE marking is accepted as supporting evidence in registration submissions. No formal relian...	REQUIRED
Estonia	YES	Estonia is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the State Agency of Medicines (SAM) does not conduc...	NOT REQUIRED
Eswatini	NO	Eswatini does not have a dedicated medical device regulatory framework or formal reliance pathway. The Eswatini Medical Supplies Department manages procurement, and WHO prequalification is used as a r...	NOT SPECIFIED
Ethiopia	PARTIAL	The Ethiopian Food and Drug Authority (EFDA) is developing its medical device regulatory framework. EFDA accepts WHO prequalification as a reference and is working toward implementing IMDRF reliance p...	REQUIRED
Finland	YES	Finland is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; Fimea (Finnish Medicines Agency) does not conduct s...	NOT REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
France	YES	France is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; ANSM (Agence nationale de sécurité du médicament et ...	NOT REQUIRED
Georgia	PARTIAL	Georgia's National Agency for Pharmacy and Logistics (NAPL) is aligning with EU regulatory standards through the EU-Georgia Association Agreement. CE-marked medical devices are broadly accepted, and t...	REQUIRED
Germany	YES	Germany is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; BfArM (Bundesinstitut für Arzneimittel und Medizinp...	NOT REQUIRED
Ghana	PARTIAL	Ghana's FDA (Food and Drugs Authority) requires medical device registration. CE marking, WHO prequalification, or FDA (US) approval is accepted as supporting evidence. Ghana is participating in AMRH h...	REQUIRED
Greece	YES	Greece is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; EOF (National Organization for Medicines) does not c...	NOT REQUIRED
Guatemala	PARTIAL	Guatemala's MSPAS (Ministerio de Salud Pública y Asistencia Social) / DRGM oversees medical device registration. FDA clearance or CE marking is accepted as supporting evidence in registration submissi...	REQUIRED
Guyana	NO	Guyana does not have a specific medical device regulatory framework or formal reliance pathway. Medical device imports are generally governed by customs regulations and basic health ministry oversight...	NOT SPECIFIED
Honduras	PARTIAL	Honduras's ARSA (Agencia de Regulación Sanitaria) oversees medical device registration. FDA clearance or CE marking is typically required as supporting documentation. A Free Sale Certificate from the ...	REQUIRED
Hong Kong	PARTIAL	Hong Kong's Medical Device Administrative Control System (MDACS) under the Medical Device Division (MDD) accepts CE marking and approvals from recognized overseas regulators (FDA, TGA, Health Canada, ...	NOT REQUIRED
Hungary	YES	Hungary is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; OGYÉI (National Institute of Pharmacy and Nutrition...	NOT REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Iceland	YES	Iceland is a member of the European Economic Area (EEA) and applies EU MDR/IVDR through the EEA Agreement. CE marking from EU/EEA-recognized notified bodies is the basis for market authorization in Ic...	NOT REQUIRED
India	YES	CDSCO (Central Drugs Standard Control Organization) has a formal reliance pathway under the Medical Devices Rules 2017 and New Drugs and Clinical Trials Rules 2019. Devices approved by FDA (US), EMA, ...	REQUIRED
Indonesia	PARTIAL	Indonesia's BPOM (Badan Pengawas Obat dan Makanan) and the Ministry of Health oversee medical device registration. As an ASEAN member, BPOM participates in AMDD harmonization and accepts CE marking, F...	REQUIRED
Iraq (Baghdad)	PARTIAL	Iraq's Ministry of Health (Central) oversees medical device imports and registration. CE marking or FDA approval is commonly required as supporting documentation, and a Free Sale Certificate is typica...	REQUIRED
Iraq (Kurdistan)	PARTIAL	The Kurdistan Regional Government's Ministry of Health follows a similar approach to the central Iraqi MOH for medical device registration. CE marking or FDA approval is referenced in the approval pro...	REQUIRED
Ireland	YES	Ireland is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; HPRA (Health Products Regulatory Authority) does no...	NOT REQUIRED
Israel	YES	Israel's Ministry of Health (MOH) / Medical Devices and Accessories Division has a formal reliance pathway that accepts CE marking and FDA approvals. Israel has a Mutual Recognition Agreement (MRA) wi...	REQUIRED
Italy	YES	Italy is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; AIFA (Agenzia Italiana del Farmaco) and the Ministry ...	NOT REQUIRED
Jamaica	NO	Jamaica does not have a specific medical device regulatory framework with a formal reliance pathway. The Ministry of Health regulates health products including devices at a basic level, typically requ...	NOT SPECIFIED
Japan	PARTIAL	Japan's PMDA (Pharmaceuticals and Medical Devices Agency) is a founding IMDRF member and has bilateral cooperation with FDA, EMA, and other regulators. However, Japan requires its own QMS audit (JPAL)...	NOT REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Jordan	PARTIAL	Jordan's Jordan Food and Drug Administration (JFDA) requires medical device registration. CE marking and FDA clearance/approval are accepted as supporting documentation and can facilitate the review p...	REQUIRED
Kazakhstan	PARTIAL	Kazakhstan is a member of the Eurasian Economic Union (EAEU) and applies the unified EAEU medical device registration system. The EAEU single-registration procedure allows devices approved in one memb...	NOT SPECIFIED
Kenya	PARTIAL	Kenya's Pharmacy and Poisons Board (PPB) / Kenya Medical Supplies Authority (KEMSA) oversees medical device regulation. Kenya is active in EAC MRH harmonization and accepts WHO prequalification and ma...	REQUIRED
Kosovo	PARTIAL	Kosovo's Agency for Medicinal Products of Kosovo (AKPM) is aligning with EU regulatory standards as part of its EU integration process. CE-marked medical devices are broadly accepted as reference, tho...	REQUIRED
Kuwait	YES	Kuwait's Ministry of Health follows the GCC harmonized medical device regulations, which accept CE marking and FDA 510(k)/PMA approvals as primary reference for registration. A single GCC-type submiss...	REQUIRED
Kyrgyzstan	PARTIAL	Kyrgyzstan is a member of the Eurasian Economic Union (EAEU) and applies the unified EAEU medical device registration system. EAEU registration allows market access across all member states; CE markin...	NOT SPECIFIED
Laos	PARTIAL	Laos's Food and Drug Department (FDD) under the Ministry of Health oversees medical device registration. As an ASEAN member, Laos participates in AMDD harmonization. Devices approved by recognized ASE...	REQUIRED
Latvia	YES	Latvia is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the State Agency of Medicines (ZVA) does not conduct...	NOT REQUIRED
Lebanon	PARTIAL	Lebanon's Ministry of Public Health (MOPH) and Directorate of Pharmaceuticals and Medical Devices require registration of medical devices. CE marking and FDA approvals are accepted as supporting docum...	REQUIRED
Liechtenstein	YES	Liechtenstein is a member of the European Economic Area (EEA) and applies EU MDR/IVDR through the EEA Agreement. CE marking from EU/EEA-recognized notified bodies is the basis for market authorization...	NOT REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Lithuania	YES	Lithuania is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the State Medicines Control Agency (SMCA) does no...	NOT REQUIRED
Luxembourg	YES	Luxembourg is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the Division de la Pharmacie et des Médicaments ...	NOT REQUIRED
Malaysia	YES	Malaysia's Medical Device Authority (MDA) has a formal reliance pathway that accepts CE marking and approvals from FDA (US), TGA (Australia), Health Canada, PMDA (Japan), and other recognized authorit...	REQUIRED
Maldives	PARTIAL	The Maldives Food and Drug Authority (MFDA) oversees medical device registration. CE marking or approvals from WHO prequalification or major reference authorities are accepted as supporting documentat...	REQUIRED
Malta	YES	Malta is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the Malta Medicines Authority (MMA) does not conduct ...	NOT REQUIRED
Mauritius	PARTIAL	The Mauritius Pharmacy Board oversees medical device registration. CE marking or approvals from recognized reference authorities (FDA, TGA) can support registration applications. No formal reliance pa...	REQUIRED
Mexico	YES	COFEPRIS (Comisión Federal para la Protección contra Riesgos Sanitarios) has a formal Accelerated Pathway (Vía Prioritaria Ampliada/VPA) that accepts prior approvals from FDA, EMA (EU), Health Canada,...	REQUIRED
Moldova	PARTIAL	Moldova's Agency of Medicines and Medical Devices (AMDM) is progressively aligning with EU regulatory standards through the EU-Moldova Association Agreement. CE-marked devices are broadly accepted, an...	REQUIRED
Mongolia	PARTIAL	Mongolia's Ministry of Health / Food, Agriculture and Light Industry Professional Inspection Agency oversees medical device imports. CE marking or approvals from major reference authorities can suppor...	REQUIRED
Montenegro	YES	Montenegro is an EU candidate country and is progressively aligning its medical device regulations with EU MDR/IVDR. The Agency for Medicines and Medical Devices (CALIMS) accepts CE-marked devices, re...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Morocco	PARTIAL	Morocco's Ministry of Health (Direction du Médicament et de la Pharmacie) requires registration of medical devices. CE marking is a key reference document for registration, and a Free Sale Certificate...	REQUIRED
Myanmar	PARTIAL	Myanmar's Food and Drug Administration (FDA Myanmar) under the Ministry of Health oversees medical device registration. As an ASEAN member, Myanmar participates in AMDD harmonization. CE marking or ap...	REQUIRED
Namibia	NO	Namibia does not have a comprehensive medical device regulatory framework or formal reliance pathway. The Namibia Medicines Regulatory Council (NMRC) is primarily focused on pharmaceuticals, and medic...	NOT SPECIFIED
Netherlands	YES	The Netherlands is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the CIBG (Central Information Point for Hea...	NOT REQUIRED
New Zealand	YES	Medsafe (New Zealand Medicines and Medical Devices Safety Authority) has a formal reliance arrangement with TGA under the Trans-Tasman Mutual Recognition Arrangement (TTMRA). Additionally, Medsafe acc...	NOT REQUIRED
Nicaragua	PARTIAL	Nicaragua's MINSA (Ministerio de Salud) oversees health product registration. FDA clearance or CE marking is typically required as supporting documentation. A Free Sale Certificate is required. No for...	REQUIRED
Nigeria	PARTIAL	NAFDAC (National Agency for Food and Drug Administration and Control) in Nigeria has developed a medical device regulatory framework. CE marking and WHO prequalification are accepted as supporting evi...	REQUIRED
North Macedonia	PARTIAL	North Macedonia's Agency for Medicines and Medical Devices (MALMED) is aligning with EU MDR/IVDR as part of EU accession. CE-marked devices are accepted, and the agency is progressively adopting EU re...	REQUIRED
Norway	YES	Norway is a member of the European Economic Area (EEA) and applies EU MDR/IVDR through the EEA Agreement. CE marking from EU/EEA-recognized notified bodies is the basis for market authorization in Nor...	NOT REQUIRED
Oman	YES	Oman's Ministry of Health follows GCC harmonized medical device regulations, which accept CE marking and FDA 510(k)/PMA approvals as primary reference for registration. As a GCC member, Oman applies t...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Pakistan	PARTIAL	Pakistan's DRAP (Drug Regulatory Authority of Pakistan) requires medical device registration. CE marking or FDA clearance/approval is accepted as supporting evidence and may qualify devices for expedi...	REQUIRED
Palestine	NO	Palestine does not have a comprehensive medical device regulatory framework with a formal reliance pathway. The Palestinian Ministry of Health manages pharmaceutical imports but formal medical device ...	NOT SPECIFIED
Panama	PARTIAL	Panama's Ministerio de Salud (MINSAL) and CSS (Caja de Seguro Social) oversee medical device regulation. FDA clearance or CE marking is accepted as supporting documentation. A Free Sale Certificate is ...	REQUIRED
Paraguay	PARTIAL	Paraguay's DNVVS (Dirección Nacional de Vigilancia Sanitaria) requires medical device registration. CE marking or FDA approval is accepted as supporting evidence. A Free Sale Certificate is commonly r...	REQUIRED
Peru	PARTIAL	Peru's DIGEMID (Dirección General de Medicamentos, Insumos y Drogas) requires medical device registration. FDA clearance, CE marking, or approvals from recognized reference authorities are accepted as...	REQUIRED
Philippines	YES	The Philippines FDA (Food and Drug Administration) has a formal Certificate of Registration system that accepts CE marking, FDA (US), TGA, and other recognized authority approvals as primary reference...	REQUIRED
Poland	YES	Poland is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the Office for Registration of Medicinal Products, M...	NOT REQUIRED
Portugal	YES	Portugal is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; INFARMED (Autoridade Nacional do Medicamento e Pro...	NOT REQUIRED
Puerto Rico	YES	Puerto Rico is a US territory and applies US FDA regulations directly. All FDA medical device requirements (510(k), PMA, De Novo) apply in Puerto Rico, making FDA clearance/approval the basis for mark...	NOT REQUIRED
Qatar	YES	Qatar's Ministry of Public Health follows GCC harmonized medical device regulations. CE marking and FDA 510(k)/PMA approvals are accepted as primary reference for device registration. As a GCC member,...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Republic of Serbia	YES	Serbia's Agency for Medicines and Medical Devices (ALIMS) is progressively aligning with EU MDR/IVDR as part of EU accession. CE-marked devices are broadly accepted and relied upon for registration. S...	REQUIRED
Romania	YES	Romania is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the National Agency for Medicines and Medical Devic...	NOT REQUIRED
Russia	NO	Russia's Roszdravnadzor (Federal Service for Surveillance in Healthcare) requires full independent national registration of medical devices and does not have a formal reliance pathway accepting FDA, E...	NOT REQUIRED
Rwanda	PARTIAL	Rwanda's Food and Drugs Authority (FDA Rwanda) accepts WHO prequalification and approvals from major reference regulators (FDA US, EMA, TGA) as supporting evidence for medical device registration. Rwa...	REQUIRED
Saudi Arabia	YES	Saudi Arabia's SFDA (Saudi Food and Drug Authority) has a formal reliance pathway under the MDMA (Medical Devices Market Authorization) framework. SFDA accepts prior approvals from FDA (US), CE markin...	REQUIRED
Senegal	NO	Senegal does not have a dedicated medical device regulatory framework with a formal reliance pathway. The Direction de la Pharmacie et du Médicament (DPM) primarily focuses on pharmaceuticals. Medical...	NOT SPECIFIED
Singapore	YES	Singapore's Health Sciences Authority (HSA) has a well-established formal reliance pathway that accepts approvals from FDA (US), EMA (EU), TGA (Australia), Health Canada, and PMDA (Japan) as primary b...	NOT REQUIRED
Slovakia	YES	Slovakia is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the State Institute for Drug Control (ŠÚKL) does n...	NOT REQUIRED
Slovenia	YES	Slovenia is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the Agency for Medicinal Products and Medical Devi...	NOT REQUIRED
South Africa	YES	SAHPRA (South African Health Products Regulatory Authority) has a formal reliance pathway that accepts prior approvals from FDA (US), EMA (EU), TGA (Australia), Health Canada, and other recognized reg...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
South Korea	YES	South Korea's MFDS (Ministry of Food and Drug Safety) has a formal abbreviated review pathway for medical devices that have already received approval from recognized reference regulators. The MFDS rec...	REQUIRED
Spain	YES	Spain is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; AEMPS (Agencia Española de Medicamentos y Productos S...	NOT REQUIRED
Sri Lanka	PARTIAL	Sri Lanka's NMRA (National Medicines Regulatory Authority) oversees medical device registration. CE marking, FDA clearance, or WHO prequalification is typically required as supporting documentation. N...	REQUIRED
Sudan	PARTIAL	Sudan's National Medicine and Poisons Board (NMPB) oversees health product regulation. CE marking or WHO prequalification may be referenced in medical device import applications. No formal reliance pa...	NOT SPECIFIED
Suriname	NO	Suriname does not have a specific medical device regulatory framework or formal reliance pathway. Basic import regulations and general health product oversight apply, without a dedicated device regist...	NOT SPECIFIED
Sweden	YES	Sweden is an EU Member State and applies EU MDR/IVDR directly. CE marking from EU-recognized notified bodies is the basis for market authorization; the Medical Products Agency (MPA/Läkemedelsverket) d...	NOT REQUIRED
Switzerland	YES	Swissmedic aligns closely with EU MDR/IVDR through the bilateral Mutual Recognition Agreement (MRA) between Switzerland and the EU. CE marking from EU-designated notified bodies is broadly accepted in...	NOT REQUIRED
Syria	NO	Syria does not have a functioning medical device regulatory framework with a formal reliance pathway. The ongoing conflict has severely disrupted regulatory infrastructure. Medical device imports are ...	NOT SPECIFIED
Taiwan	YES	Taiwan's TFDA (Taiwan Food and Drug Administration) has a formal expedited review pathway for medical devices with prior approval from recognized reference regulators. TFDA accepts FDA (US) 510(k)/PMA...	REQUIRED
Tanzania	PARTIAL	Tanzania's TMDA (Tanzania Medicines and Medical Devices Authority) accepts WHO prequalification and approvals from major reference regulators (FDA, EMA) as supporting evidence for medical device regis...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Thailand	PARTIAL	Thailand's FDA (TFDA/Thai FDA) under the Ministry of Public Health oversees medical device registration. As an ASEAN member, Thailand participates in AMDD harmonization. CE marking, FDA, or recognized...	REQUIRED
Tunisia	PARTIAL	Tunisia's DHMPE (Direction de l'Hygiène du Milieu et de la Protection de l'Environnement) under the Ministry of Health requires medical device registration. CE marking is a key reference document and ...	REQUIRED
Turkey	YES	Turkey's TITCK (Turkish Medicines and Medical Devices Agency) has aligned its medical device regulations closely with EU MDR/IVDR. CE marking from EU-recognized notified bodies is broadly accepted and...	REQUIRED
Turkmenistan	NO	Turkmenistan does not have a comprehensive medical device regulatory framework or formal reliance pathway. Medical device regulation is minimal and managed through general health ministry oversight. N...	NOT SPECIFIED
Uganda	PARTIAL	Uganda's National Drug Authority (NDA) oversees pharmaceutical and medical device regulation. NDA accepts WHO prequalification and approvals from major reference regulators as supporting evidence. Uga...	REQUIRED
Ukraine	PARTIAL	Ukraine's State Expert Centre (SEC) under the Ministry of Health is progressively aligning with EU regulations through the EU-Ukraine Association Agreement. CE-marked medical devices are broadly accep...	REQUIRED
United Arab Emirates	YES	The UAE has a multi-level medical device regulatory framework: the federal MOH, Dubai Health Authority (DHA), and Abu Dhabi Department of Health (DOH). All authorities accept CE marking and FDA 510(k)...	REQUIRED
United Kingdom	YES	The MHRA (Medicines and Healthcare products Regulatory Agency) has a formal reliance pathway under the UK CA marking scheme. MHRA formally recognizes and relies on decisions from designated reference ...	NOT REQUIRED
United States of America	YES	The US FDA is a primary reference authority for global medical device reliance pathways rather than a reliance-pathway country itself. FDA participates in IMDRF, MDSAP, and bilateral arrangements (wit...	NOT REQUIRED
Uruguay	PARTIAL	Uruguay's MSP (Ministerio de Salud Pública) / Department of Medical Devices requires registration. FDA clearance, CE marking, or ANMAT (Argentina) approval can support the registration dossier and may...	REQUIRED

Country Analysis (continued)

Country	Pathway	Description	FSC Required
Venezuela	NO	Venezuela's MPPS (Ministerio del Poder Popular para la Salud) has a medical device registration system, but the regulatory framework has been significantly weakened due to the political and economic c...	NOT SPECIFIED
Vietnam	PARTIAL	Vietnam's Drug Administration of Vietnam (DAV) under the Ministry of Health oversees medical device registration. As an ASEAN member, Vietnam participates in AMDD harmonization. CE marking and FDA app...	REQUIRED
Yemen	NO	Yemen does not have a functioning medical device regulatory framework with a formal reliance pathway. The ongoing conflict has severely disrupted regulatory infrastructure, and the Ministry of Public ...	NOT SPECIFIED
Zimbabwe	PARTIAL	Zimbabwe's MCAZ (Medicines Control Authority of Zimbabwe) oversees pharmaceutical and medical device regulation. MCAZ accepts WHO prequalification and approvals from major reference regulators (FDA, E...	REQUIRED

Special Chapter: Regional Regulatory Groupings

The following regional bodies and groupings do not represent individual sovereign states but play a significant role in shaping reliance frameworks. Some regional harmonization initiatives formally define reliance criteria; others are aspirational or informational in nature.

Region / Body	Pathway	Description	FSC
ASEAN (Regional)	YES	ASEAN has the ASEAN Medical Device Directive (AMDD) framework which harmonizes medical device regulations across member states. The framework encourages reliance on decisions from recognized reference...	NOT SPECIFIED
Africa (Regional)	PARTIAL	The African Medicines Regulatory Harmonization (AMRH) initiative under the African Union Development Agency (AUDA-NEPAD) is building a continental harmonization framework. The African Medicines Agency...	NOT SPECIFIED
Americas (Regional)	PARTIAL	PANDRH (Pan American Network on Drug Regulatory Harmonization) under PAHO promotes reliance among Americas countries. Several member states have adopted IMDRF principles and use reliance on FDA, Healt...	NOT SPECIFIED
Asia-Pacific (Regional)	PARTIAL	The Asia Pacific Economic Cooperation (APEC) has the Life Sciences Innovation Forum (LSIF) that promotes regulatory convergence and reliance among member economies. Several APEC economies actively par...	NOT SPECIFIED
Caribbean (Regional)	PARTIAL	CARICOM (Caribbean Community) has pharmaceutical harmonization efforts under PANDRH but medical device-specific reliance pathways are not fully developed across the region. Individual Caribbean nation...	NOT SPECIFIED
East Africa (Regional)	PARTIAL	The East African Community (EAC) has the EAC Medicines Regulatory Harmonization (MRH) program under the EAC Medicines and Food Safety Commission (EAMFC). The framework promotes reliance on reference r...	NOT SPECIFIED
Europe (Regional)	YES	The European Economic Area (EEA) applies EU MDR/IVDR, the most comprehensive harmonized regulatory framework in the world for medical devices. CE marking issued by EU/EEA-recognized notified bodies se...	NOT REQUIRED
European Union	YES	The EU MDR (Medical Device Regulation 2017/745) and IVDR (2017/746) create a unified regulatory framework across all EU member states. CE marking from EU-designated notified bodies is required and con...	NOT REQUIRED
Global	YES	The IMDRF (International Medical Device Regulators Forum) has established global principles and guidelines for regulatory reliance (IMDRF/RPS WG/N55). These guidelines provide the international framew...	NOT SPECIFIED
Gulf Region (Regional)	YES	The Gulf Cooperation Council (GCC) has harmonized medical device regulations through the GCC Medical Device Technical Regulations (MDTR). The unified framework accepts CE marking and FDA 510(k)/PMA ap...	REQUIRED
International	YES	IMDRF (International Medical Device Regulators Forum) promotes global reliance principles allowing regulators to rely on each other's decisions. WHO's Medical Device Prequalification Programme also pr...	NOT SPECIFIED
Middle East (Regional)	PARTIAL	The Middle East lacks a single unified regulatory framework for medical devices beyond the GCC. GCC member states share harmonized medical device regulations (MDTR) that rely on CE/FDA approvals. Non-...	NOT SPECIFIED

Special Chapter: Countries Without Reliance Pathways

The following **17** countries currently have **no formal reliance pathway** for medical devices. These markets typically require full standalone registration without leveraging prior approvals from reference authorities. Manufacturers should expect longer review timelines and more documentation-intensive submissions in these markets.

⚠ High-Burden Registration Markets

Markets with no reliance pathways require manufacturers to submit complete technical dossiers, local clinical/performance data (in some cases), in-country representation, and full regulatory review from scratch — even when FDA 510(k), CE, or TGA approval already exists.

Country	Notes	FSC
Afghanistan	Afghanistan does not have a formal medical device regulatory framework or reliance pathway. The Ministry of Public Health oversees medicines but medical devices are largely unregulated with no formal reliance mechanism e...	NOT SPECIFIED
Belize	Belize does not have a specific medical device regulatory framework or formal reliance pathway. Medical device imports are generally managed through customs and import regulations without a dedicated device approval proc...	NOT SPECIFIED
Benin	Benin does not have a dedicated medical device regulatory framework. The country relies on broader pharmaceutical regulations and WHO prequalification where applicable, but no formal reliance pathway for medical devices ...	NOT SPECIFIED
Cuba	Cuba's CECMED (Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos) conducts independent national review of medical devices and does not have a formal reliance pathway. The regulatory system re...	NOT SPECIFIED
Côte d'Ivoire	Côte d'Ivoire does not have a dedicated medical device regulatory framework or formal reliance pathway. The regulatory framework for medical devices is minimal, with WAEMU (West African Economic and Monetary Union) harmo...	NOT SPECIFIED
Eswatini	Eswatini does not have a dedicated medical device regulatory framework or formal reliance pathway. The Eswatini Medical Supplies Department manages procurement, and WHO prequalification is used as a reference for quality...	NOT SPECIFIED
Guyana	Guyana does not have a specific medical device regulatory framework or formal reliance pathway. Medical device imports are generally governed by customs regulations and basic health ministry oversight without a dedicated...	NOT SPECIFIED
Jamaica	Jamaica does not have a specific medical device regulatory framework with a formal reliance pathway. The Ministry of Health regulates health products including devices at a basic level, typically requiring FDA or CE appr...	NOT SPECIFIED
Namibia	Namibia does not have a comprehensive medical device regulatory framework or formal reliance pathway. The Namibia Medicines Regulatory Council (NMRC) is primarily focused on pharmaceuticals, and medical device regulation...	NOT SPECIFIED
Palestine	Palestine does not have a comprehensive medical device regulatory framework with a formal reliance pathway. The Palestinian Ministry of Health manages pharmaceutical imports but formal medical device registration with re...	NOT SPECIFIED
Russia	Russia's Roszdravnadzor (Federal Service for Surveillance in Healthcare) requires full independent national registration of medical devices and does not have a formal reliance pathway accepting FDA, EMA, or other foreign...	NOT REQUIRED
Senegal	Senegal does not have a dedicated medical device regulatory framework with a formal reliance pathway. The Direction de la Pharmacie et du Médicament (DPM) primarily focuses on pharmaceuticals. Medical device regulation i...	NOT SPECIFIED