



Reliance Pathway Report

Global Medical Device Market Analysis — 146 Markets

57

Reliance Pathway
EXISTS

59

Reliance Pathway
PARTIAL

17

No Reliance
Pathway

13

Regional
Bodies

Report Scope

This report analyses medical device regulatory reliance pathways across **133 sovereign markets** and **13 regional bodies** served by RegDesk. Three key questions are addressed for each market:

Q1 — Does a reliance pathway exist? | **Q2** — Description of the pathway | **Q3** — Is FSC/Certificate of Good Standing required?



Sovereign Markets — Countries A–Z (Page 1 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 reliance mechanism established.	N/S
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 decisions as part of its EU alignment process.	YES
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 the dossier submission and may expedite review.	YES
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 registration. The 'Reconocimiento de Certificados Extranjeros' process allows abbreviated review based on recognized foreign approvals.	YES
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 on FDA/EMA decisions; however, CE marking is viewed favorably in practice.	YES
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 ARTG inclusion. The pathway significantly reduces regulatory burden and review time for higher-class devices.	NO
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 conduct separate product reviews for CE-marked devices.	NO
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 Certificate from the country of manufacture is commonly required.	YES
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 Cooperation Council (GCC) harmonized medical device regulations which incorporate reliance principles.	YES
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 supporting evidence. A Free Sale Certificate from the exporting country is mandatory.	YES



Sovereign Markets — Countries A–Z (Page 2 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 rely on FDA/EMA decisions; a single EAEU registration certificate allows market access across member states.	N/S
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 conduct separate product-level reviews for CE-marked devices.	NO
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 device approval process.	N/S
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 for medical devices exists.	N/S
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 reliance procedure is defined. A Free Sale Certificate from the reference country is commonly required.	YES
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 agency relying on EU notified body decisions for conformity assessment.	YES
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 regulator approvals (FDA, EMA) as supporting evidence for registration, but no formal reliance pathway has been officially codified.	YES
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. Devices approved by these authorities qualify for accelerated registration review in Brazil.	YES
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 additional national product approval beyond CE marking.	NO
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 approval from recognized ASEAN reference authorities can support registration, and a Certificate of Free Sale is typically required.	YES



Sovereign Markets — Countries A–Z (Page 3 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 regulatory framework for medical devices is limited and not fully codified.	N/S
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 that replaces Canadian registration with a foreign approval, Health Canada uses foreign regulatory information to inform and expedite its own reviews.	NO
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 facilitate a more streamlined review, but there is no formal reliance pathway that automatically expedites approval.	YES
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 jurisdictions, but China requires its own full technical review and does not formally rely on foreign regulatory decisions. Some recognition of international standards (ISO, IEC) is incorporated.	NO
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 devices already approved by recognized authorities. No automatic recognition pathway exists, but review is significantly shorter.	YES
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 exists, but reference approvals facilitate faster administrative processing.	YES
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 Medical Devices (HALMED) does not require separate national product approval.	NO
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 regulatory system requires full independent technical evaluation of all devices.	N/S
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 requirement beyond what EU law specifies.	NO
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) does not conduct separate national product reviews for CE-marked devices.	NO



Sovereign Markets — Countries A–Z (Page 4 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 Monetary Union) harmonization efforts still at an early stage.	N/S
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 separate national product reviews for CE-marked devices.	NO
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 Free Sale Certificate is typically required. There is no formal reliance pathway.	YES
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 support the application dossier and may reduce review time. No formal reliance pathway is codified.	YES
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 can facilitate review. A formal reliance pathway exists for some device classes under the expedited approval program.	YES
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 reliance pathway exists but reference approvals facilitate the process.	YES
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 conduct separate national product reviews for CE-marked devices.	NO
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 reference for quality assurance, but no formal device reliance pathway is established.	N/S
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 principles, but no formal reliance pathway for medical devices is fully operational yet.	YES
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 separate national product reviews for CE-marked devices.	NO



Sovereign Markets — Countries A–Z (Page 5 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 des produits de santé) does not conduct separate national product reviews for CE-marked devices.	NO
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 the agency relies on EU technical documentation standards, though a formal codified reliance pathway is not yet fully established.	YES
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 Medizinprodukte) does not conduct separate national product reviews for CE-marked devices. Germany hosts several major EU notified bodies.	NO
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 harmonization efforts which will further develop reliance pathways. No fully formal reliance pathway is currently codified.	YES
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 conduct separate national product reviews for CE-marked devices.	NO
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 submissions. A Free Sale Certificate is typically required. No formal reliance pathway exists.	YES
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 without a dedicated approval process.	N/S
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 country of origin is mandatory. No formal reliance pathway replaces local registration.	YES
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, PMDA) as supporting evidence for device listing. While not a full reliance pathway, MDACS Class II-IV devices require reference to such approvals.	NO
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) does not conduct separate national product reviews for CE-marked devices.	NO



Sovereign Markets — Countries A–Z (Page 6 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 Iceland, with the Icelandic Medicines Agency (IMA) overseeing compliance.	NO
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, TGA (Australia), Health Canada, PMDA (Japan), and other ICH/recognized regulators qualify for expedited registration review in India.	YES
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, FDA, or recognized ASEAN authority approvals as supporting evidence. Priority review may be granted for devices with reference approvals.	YES
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 typically needed. No formal codified reliance pathway exists, but reference approvals are used to facilitate import authorization.	YES
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 process, and a Free Sale Certificate is typically required.	YES
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 not conduct separate national product reviews for CE-marked devices.	NO
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) with the EU for pharmaceutical GMP and aligns closely with EU MDR for medical devices, with an expedited pathway for CE-marked devices.	YES
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 of Health do not conduct separate national product reviews for CE-marked devices.	NO
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 requiring FDA or CE approval as a reference but without a codified reliance procedure.	N/S
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) and technical review; foreign regulatory approvals can provide supporting evidence but do not replace Japanese registration requirements.	NO



Sovereign Markets — Countries A–Z (Page 7 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 process. A Free Sale Certificate from the country of manufacture is commonly required.	YES
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 member state to access all EAEU markets. CE marking is viewed favorably but does not replace EAEU registration.	N/S
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 major reference regulator approvals (FDA, EMA) as supporting evidence. A formal reliance pathway is still developing.	YES
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, though a formal codified reliance pathway has not been fully established. EU MDR alignment is the stated regulatory direction.	YES
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 submission with CE/FDA documentation forms the basis for Kuwaiti registration.	YES
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 marking can be referenced but does not replace EAEU registration.	N/S
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 ASEAN reference authorities or with CE/FDA approval can support the registration process.	YES
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 separate national product reviews for CE-marked devices.	NO
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 documentation. A Free Sale Certificate is commonly required. No formal codified reliance pathway exists.	YES
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, with the Office for Health (Amt für Gesundheit) overseeing compliance.	NO



Sovereign Markets — Countries A–Z (Page 8 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 not conduct separate national product reviews for CE-marked devices.	NO
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 does not conduct separate national product reviews for CE-marked devices.	NO
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 authorities as supporting evidence for expedited registration. MDSAP audit certificates are also recognized. Malaysia actively participates in ASEAN AMDD harmonization.	YES
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 documentation. No formal reliance pathway is codified.	YES
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 separate national product reviews for CE-marked devices.	NO
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 pathway has been codified, but reference approvals are generally required.	YES
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, TGA, and PMDA to significantly expedite medical device registration in Mexico. The pathway allows for abbreviated technical review based on reference regulator decisions.	YES
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, and EU MDR technical documentation standards are being adopted. A formal codified reliance pathway is still developing.	YES
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 support the import/registration process. No formal reliance pathway is codified.	YES
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, relying on EU notified body decisions as part of the EU accession alignment process.	YES



Sovereign Markets — Countries A–Z (Page 9 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 is typically required. Morocco follows a review process that considers CE documentation but no formal automatic reliance pathway is established.	YES
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 approvals from recognized ASEAN reference authorities can support registration. A Free Sale Certificate is typically required.	YES
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 medical device regulation is at an early stage of development.	N/S
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 Healthcare Professions) / IGJ (Inspectorate) does not conduct separate national product reviews for CE-marked devices.	NO
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 accepts evidence of approval from TGA, FDA, EMA, Health Canada, PMDA, and UK MHRA to streamline New Zealand medical device registration.	NO
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 formal reliance pathway is codified.	YES
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 evidence. NAFDAC is working toward implementing AMRH reliance principles. No fully formal reliance pathway is yet operational.	YES
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 regulatory standards. A formal codified reliance pathway is developing.	YES
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 Norway, with the Norwegian Medicines Agency (NOMA) overseeing compliance.	NO
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 the GCC Medical Device Technical Regulations (MDTR) framework.	YES



Sovereign Markets — Countries A–Z (Page 10 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 expedited review. A Free Sale Certificate is typically required. No fully formal reliance pathway has been codified.	YES
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 registration with reliance procedures is not established.	N/S
Panama	PARTIAL	Panama's Ministerio de Salud (MINSa) 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 commonly required. No formal reliance pathway exists.	YES
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 required. No formal reliance pathway is codified.	YES
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 supporting documentation. A Free Sale Certificate is required. An expedited pathway exists for devices with strong reference approvals.	YES
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. The FDA Philippines offers an expedited review pathway for devices with prior reference regulator approval, and participates in ASEAN AMDD harmonization.	YES
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, Medical Devices and Biocidal Products (URPL) does not conduct separate national product reviews for CE-marked devices.	NO
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 Produtos de Saúde) does not conduct separate national product reviews for CE-marked devices.	NO
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 market access. No separate registration is required beyond FDA requirements.	NO
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, Qatar applies the GCC Medical Device Technical Regulations (MDTR) framework.	YES



Sovereign Markets — Countries A–Z (Page 11 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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. Serbia has published regulations closely mirroring EU MDR, making CE marking the primary basis for device approval.	YES
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 Devices (ANMMDR) does not conduct separate national product reviews for CE-marked devices.	NO
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, EMA, or other foreign approvals. Russia has its own comprehensive regulatory system with mandatory Russian-specific technical review and testing.	NO
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. Rwanda is active in EAC MRH harmonization efforts and is developing its formal reliance framework.	YES
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 marking (EU), TGA (Australia), Health Canada, and PMDA (Japan) as primary basis for expedited registration review.	YES
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 device regulation is minimal, with WAEMU harmonization efforts still at an early stage.	N/S
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 basis for expedited Class B, C, and D medical device registration. HSA is itself recognized as a reference authority by other regulators.	NO
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 not conduct separate national product reviews for CE-marked devices.	NO
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 Devices (JAZMP) does not conduct separate national product reviews for CE-marked devices.	NO
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 recognizes FDA 510(k)/PMA, CE marking (EU), and TGA approvals for expedited review, and participates in IMDRF and MDSAP.	YES



Sovereign Markets — Countries A–Z (Page 12 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 Sanitarios) does not conduct separate national product reviews for CE-marked devices.	NO
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. No formal reliance pathway is codified, but reference approvals facilitate the review process.	YES
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 pathway is established, and the regulatory framework for medical devices is minimal.	N/S
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 registration or approval process.	N/S
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) does not conduct separate national product reviews for CE-marked devices.	NO
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 Switzerland, and Swissmedic conducts its review based on EU-aligned technical standards and notified body certificates.	NO
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 managed through limited Ministry of Health oversight without a codified approval or reliance process.	N/S
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, CE marking, and approvals from PMDA (Japan) as basis for abbreviated review in its recognition-based registration pathway.	YES
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 registration. Tanzania is active in EAC MRH harmonization and is developing its formal reliance framework.	YES
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 ASEAN authority approvals can support registration and may qualify devices for a shortened review timeline.	YES



Sovereign Markets — Countries A–Z (Page 13 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 is generally required for registration. A Free Sale Certificate is typically required. No formal reliance pathway is codified.	YES
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 serves as the primary basis for Turkish medical device registration. Turkey has adopted EU-equivalent MDR requirements into national law.	YES
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. No formally codified reliance procedure has been established.	N/S
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. Uganda is active in EAC MRH harmonization efforts. A formal reliance pathway for medical devices is still developing.	YES
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 accepted, and EU MDR documentation standards are being adopted. A formal codified reliance pathway is developing.	YES
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)/PMA as primary reference for registration. As a GCC member, UAE applies GCC Medical Device Technical Regulations (MDTR) with formal reliance on CE/FDA approvals.	YES
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 regulators (FDA, EMA, TGA, Health Canada) for expedited review. The UK Approved Body certification process for UK CA marking can use EU MDR CE certificates during the transition period.	NO
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 (with EU, Health Canada, Japan, etc.) that inform its review processes. FDA's 510(k)/PMA/De Novo pathways are the reference standard used by other countries in their reliance frameworks.	NO
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 qualify for expedited review. A Free Sale Certificate is commonly required. No formal automatic reliance pathway is codified.	YES
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 crisis. Practical enforcement and formal reliance pathways are non-functional in the current environment.	N/S



Sovereign Markets — Countries A–Z (Page 14 of 14)

Country	Q1: Exists?	Q2: Pathway Description	Q3: FSC?
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 approvals are accepted as supporting documentation. A Free Sale Certificate is typically required. No fully formal reliance pathway is codified.	YES
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 Health and Population operates with very limited capacity for device regulation.	N/S
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, EMA, SAHPRA) as supporting evidence. An abbreviated review pathway is available for WHO-prequalified products. A formal device-specific reliance pathway is still developing.	YES



Special Chapter — Regional Bodies & Harmonization Frameworks

These 13 entries represent regional regulatory frameworks and harmonization bodies rather than sovereign nations. Individual member states may have their own national reliance policies in addition to these regional frameworks.

Regional Body	Q1: Exists?	Q2: Framework Description	Q3: 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 authorities (FDA, EMA, TGA) and promotes mutual recognition among ASEAN members. The ASEAN Harmonized Technical Requirements (AHWP) further supports reliance-based submissions.	N/S
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 (AMA), established in 2021, aims to facilitate reliance-based reviews across African nations, but implementation for medical devices is still in early stages.	N/S
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, Health Canada, or ANVISA decisions to expedite national approvals.	N/S
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 participate in IMDRF and implement reliance pathways based on reference regulator decisions.	N/S
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 nations largely rely on FDA, EMA, or UK MHRA approvals as de facto reference standards for import.	N/S
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 regulator decisions and WHO prequalification for expedited registration across EAC member states.	N/S
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 serves as the basis for market access across all 30 EEA member states, constituting a full regional reliance system.	NO
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 constitutes the basis for market access in all 27 EU member states without additional national product approval.	NO
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 framework that national regulators use to implement reliance pathways, recognizing decisions by reference authorities such as FDA, EMA, TGA, Health Canada, and PMDA.	N/S
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 approvals as primary reference, with a single GCC registration allowing market access across all six member states.	YES
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 provides an international reliance mechanism for low/middle-income countries to access pre-evaluated devices.	N/S
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-GCC Middle Eastern countries (e.g., Lebanon, Jordan, Iraq) individually use CE/FDA documentation as reference but without formal reliance pathways.	N/S
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 regulators. SAHPRA uses these reference decisions to inform and expedite local review, with an abbreviated assessment pathway for reference-approved devices.	YES