



Reliance Pathway Report

Medical Device Regulatory Intelligence — 124 Countries + Regional Frameworks

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62

Formal Pathway
Established reliance

67

Partial Pathway
Elements present

17

Unknown
Limited data

146

Total Entries
Countries + Regions

About This Report

This report maps the regulatory reliance pathway landscape for medical devices across all 146 countries and regional bodies served by RegDesk. It answers three key questions for each market:

- **Q1 — Pathway Exists?** Whether a formal or informal reliance mechanism is in place
- **Q2 — Description:** Brief overview of how the reliance pathway works in practice
- **Q3 — FSC/CGF Required?** Whether a Free Sale Certificate or Certificate of Good Standing is needed

Note on Regional Bodies: Entries such as ASEAN, EU, Gulf Region, Africa Regional, etc. represent supranational frameworks rather than individual countries. These are presented in a dedicated chapter at the end of this report, along with countries where no reliance criteria were identified.

Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
Afghanistan	UNKNOWN	Afghanistan has a very limited regulatory framework for medical devices. No formal reliance pathway has been established. The Ministry of Public Health has minimal capacity for independent device review.	UNKNOWN
Albania	PARTIAL	Albania is an EU candidate country and is progressively aligning its medical device regulations with EU MDR/IVDR. The Agency for Medicines and Medical Devices (AKBM) accepts CE-marked devices as part of the pre-accession harmonization process.	SOMETIMES
Algeria	PARTIAL	Algeria's Ministry of Health regulates medical devices through the National Agency for Pharmaceutical Products (ANPP). There is a partial reliance on foreign approvals (FDA, CE) as supporting evidence, but a full independent national review is typically still required.	YES
Argentina	YES	ANMAT (National Administration of Drugs, Food and Medical Technology) has a reliance pathway that accepts prior approvals from recognized regulators (FDA, CE, ANVISA) to streamline the authorization process. Manufacturers can leverage foreign approvals as supporting documentation.	YES
Armenia	YES	Armenia is a member of the Eurasian Economic Union (EAEU) and follows the EAEU medical device regulation framework. Devices registered in one EAEU member state can be recognized in others, providing a formal intra-union reliance pathway.	SOMETIMES
Australia	YES	Australia's TGA (Therapeutic Goods Administration) has the ARES (Abridged Review for Similar/Established devices) pathway and accepts evidence from comparable overseas regulators including the FDA, EMA, Health Canada, and Japan's PMDA. The TGA also participates in MDSAP.	SOMETIMES
Austria	YES	Austria is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). CE marking issued by a Notified Body is the required pathway; there is no separate national approval process for devices already CE-marked.	NO
Azerbaijan	PARTIAL	Azerbaijan's Ministry of Health and the Agency for Medicines (TABIB) regulate medical devices. The country is not part of EAEU but may accept international regulatory approvals as supporting evidence. The formal reliance framework is limited and developing.	SOMETIMES
Bahrain	YES	The National Health Regulatory Authority (NHRA) in Bahrain follows the GCC (Gulf Cooperation Council) harmonized framework for medical device registration and accepts FDA/CE approvals as the basis for registration. Bahrain participates in the GCC Central Registration program.	YES
Bangladesh	PARTIAL	The Directorate General of Drug Administration (DGDA) regulates medical devices in Bangladesh. A formal reliance pathway is not well-established, but regulatory submissions typically require evidence of foreign regulatory approval (FDA, CE, WHO Prequalification) as supporting documentation.	YES
Belarus	YES	Belarus is a member of the Eurasian Economic Union (EAEU) and follows the EAEU medical device regulatory framework. Devices registered under the EAEU single registration certificate are valid across all member states including Belarus.	SOMETIMES
Belgium	YES	Belgium is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Federal Agency for Medicines and Health Products (FAMHP) oversees implementation. CE marking is the required pathway.	NO
Belize	UNKNOWN	Belize has a very limited regulatory framework for medical devices. The Ministry of Health regulates health products but no formal medical device registration or reliance pathway has been established.	UNKNOWN
Benin	UNKNOWN	Benin has minimal regulatory infrastructure for medical devices. The Ministry of Health oversees health product regulation but no formal device registration or reliance pathway exists.	UNKNOWN

Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
Bulgaria	YES	Bulgaria is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). CE marking issued by a Notified Body is the required pathway; no separate national approval is needed for CE-marked devices.	NO
Cambodia	PARTIAL	The Department of Drug and Food (DDF) under Cambodia's Ministry of Health regulates medical devices. Cambodia participates in the ASEAN Medical Device Directive framework. Registration typically requires evidence of approval from the country of origin. Regulatory capacity is still developing.	YES
Cameroon	UNKNOWN	Cameroon's Ministry of Public Health regulates health products but has very limited formal regulatory infrastructure for medical devices. No established reliance pathway has been identified.	UNKNOWN
Canada	YES	Health Canada has a formal reliance pathway where it can rely on reviews conducted by trusted foreign regulators (FDA, EMA, TGA, PMDA) to inform its own decision-making. Canada also participates in MDSAP (Medical Device Single Audit Program) which enables recognition of audits across multiple jurisdictions.	SOMETIMES
Chile	YES	The ISP (Instituto de Salud Pública de Chile) has a reliance pathway that accepts prior approvals from recognized regulatory authorities (FDA, CE, ANVISA, Health Canada, TGA) to expedite medical device registration. Evidence of foreign approval is a key component of the registration dossier.	YES
China	PARTIAL	The NMPA (National Medical Products Administration) has priority review and innovative device designation pathways, but does not formally rely on foreign regulatory approvals. China conducts its own independent technical reviews. Clinical data from Chinese trials is typically required for Class III devices.	SOMETIMES
Colombia	YES	INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos) has a reliance pathway that accepts prior approvals from benchmark regulatory authorities (FDA, EMA, Health Canada, TGA, ANVISA) to expedite device registration in Colombia. The reliance process significantly reduces review timelines.	YES
Costa Rica	PARTIAL	The Ministry of Health (DCTM) regulates medical devices in Costa Rica. Foreign regulatory approvals from recognized authorities are accepted as supporting documentation. A formal structured reliance pathway exists but is not fully developed.	YES
Croatia	YES	Croatia is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Agency for Medicinal Products and Medical Devices (HALMED) oversees implementation. CE marking is the required pathway.	NO
Cuba	PARTIAL	CECMED (Centro para el Control Estatal de Medicamentos, Equipos y Dispositivos Médicos) regulates medical devices in Cuba. Cuba maintains an independent regulatory system with limited formal reliance on foreign regulatory decisions. The regulatory process is generally more restrictive.	UNKNOWN
Cyprus	YES	Cyprus is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Pharmaceutical Services of the Ministry of Health oversees implementation. CE marking is the required pathway.	NO
Czech Republic	YES	Czech Republic is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The State Institute for Drug Control (SUKL) oversees medical device vigilance. CE marking is the required pathway.	NO
Côte d'Ivoire	UNKNOWN	Côte d'Ivoire's Ministry of Health and Public Hygiene regulates health products but has very limited formal regulatory infrastructure for medical devices. No established reliance pathway has been identified.	UNKNOWN
Denmark	YES	Denmark is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Danish Medicines Agency (DKMA) oversees implementation. CE marking is the required pathway.	NO

DIGEMAPS (Dirección General de Medicamentos, Alimentos y Productos Sanitarios)



Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
Estonia	YES	Estonia is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The State Agency of Medicines (SAM) oversees implementation. CE marking is the required pathway.	NO
Eswatini	UNKNOWN	Eswatini's Ministry of Health regulates health products but has very limited regulatory capacity for medical devices. No formal reliance pathway for medical devices has been established.	UNKNOWN
Ethiopia	PARTIAL	The Ethiopian Food and Drug Authority (EFDA) regulates medical devices and is building regulatory capacity. Foreign regulatory approvals (FDA, CE, WHO) are used as supporting evidence in registration dossiers. A formal structured reliance pathway is still developing.	YES
Finland	YES	Finland is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). Fimea (Finnish Medicines Agency) oversees implementation. CE marking is the required pathway.	NO
France	YES	France is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). ANSM (Agence nationale de sécurité du médicament et des produits de santé) oversees vigilance and implementation. CE marking is the required pathway.	NO
Georgia	PARTIAL	The National Agency for Pharmacy and Medical Technologies (NAPM) regulates medical devices in Georgia. The country is aligned with the EU Association Agreement and is progressively harmonizing with EU standards. CE marking is recognized, but a national registration process is still required.	SOMETIMES
Germany	YES	Germany is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). BfArM and the Federal Institute for Drugs and Medical Devices oversee implementation. CE marking is the required pathway.	NO
Ghana	PARTIAL	The Food and Drugs Authority (FDA Ghana) regulates medical devices and has provisions for reliance on approvals from recognized international regulatory authorities (FDA, EMA, WHO). Internationally approved devices receive expedited review, but a national registration is still required.	YES
Greece	YES	Greece is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The National Organization for Medicines (EOF) oversees vigilance. CE marking is the required pathway.	NO
Guatemala	PARTIAL	The Department of Health Regulation and Control (DRCA) under Guatemala's Ministry of Health regulates medical devices. Foreign regulatory approvals are accepted as supporting documentation, but a formal structured reliance pathway is limited.	YES
Guyana	UNKNOWN	Guyana's Food and Drug Department under the Ministry of Health regulates health products but has very limited capacity for medical device regulation. No formal reliance pathway for medical devices has been established.	UNKNOWN
Honduras	PARTIAL	The Ministry of Health (SESAL) regulates medical devices in Honduras. Foreign regulatory approvals from recognized authorities are accepted as supporting documentation. A formal structured reliance pathway is limited.	YES
Hong Kong	YES	Hong Kong's Medical Device Administrative Control System (MDACS) operated by the Medical Device Division accepts devices listed on the registers of comparable overseas regulators (FDA, EMA, TGA, Health Canada) for expedited inclusion on the Hong Kong register. This constitutes a formal reliance pathway.	SOMETIMES
Hungary	YES	Hungary is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The National Institute of Pharmacy and Nutrition (OGYÉI) oversees implementation. CE marking is the required pathway.	NO
Iceland	YES	Iceland is an EEA member and follows EU MDR and IVDR framework through the EEA Agreement. The Icelandic Medicines Agency (IMA) oversees implementation. CE	NO

Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
Iraq (Kurdistan)	UNKNOWN	The Kurdistan Regional Government's Ministry of Health operates semi-independently but has very limited regulatory capacity for medical devices. No formal medical device reliance pathway has been established.	UNKNOWN
Ireland	YES	Ireland is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Health Products Regulatory Authority (HPRA) oversees implementation. CE marking is the required pathway.	NO
Israel	YES	Israel's Ministry of Health Medical Devices Division (MDD) has a reliance pathway for medical devices that accepts prior approvals from recognized regulatory authorities (FDA, CE, Health Canada, TGA) to expedite registration. The AMAR (Abbreviated Medical Device Registration) pathway is specifically designed for this purpose.	SOMETIMES
Italy	YES	Italy is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Italian Medicines Agency (AIFA) and the Ministry of Health oversee implementation. CE marking is the required pathway.	NO
Jamaica	UNKNOWN	Jamaica's Ministry of Health regulates health products but has very limited formal regulatory infrastructure for medical devices. No established reliance pathway for medical devices has been identified.	UNKNOWN
Japan	PARTIAL	Japan's PMDA (Pharmaceuticals and Medical Devices Agency) conducts largely independent technical reviews under the Act on Securing Quality, Efficacy and Safety of Products. Japan has been a founding member of IMDRF and participates in MDSAP, allowing some reliance on foreign audit data, but clinical data from Japanese patients may still be required.	SOMETIMES
Jordan	YES	The Jordan Food and Drug Administration (JFDA) has a reliance pathway for medical devices that accepts prior approvals from recognized regulatory authorities (FDA, CE, Health Canada) as the basis for expedited registration. Devices approved by benchmark regulators receive a simplified review process.	YES
Kazakhstan	YES	Kazakhstan is a member of the Eurasian Economic Union (EAEU) and follows the EAEU medical device regulatory framework. Devices with a single EAEU registration certificate are valid across all member states. Kazakhstan's Ministry of Health also participates in the EAEU mutual recognition process.	SOMETIMES
Kenya	PARTIAL	The Pharmacy and Poisons Board (PPB) of Kenya regulates medical devices and participates in the EAC harmonization program. International regulatory approvals (FDA, CE, WHO) are accepted as part of registration dossiers, but a national registration process is still conducted.	YES
Kosovo	PARTIAL	The Kosovo Medicines and Medical Devices Agency (KAMMDA) regulates medical devices and is progressively aligning with EU standards as part of Kosovo's European integration aspirations. CE marking is generally accepted, but a national registration process is maintained.	SOMETIMES
Kuwait	YES	Kuwait's Ministry of Health participates in the GCC harmonized medical device registration framework. FDA and CE approvals are accepted as the basis for registration. The GCC Central Registration program provides a pathway for devices already approved by recognized regulators.	YES
Kyrgyzstan	YES	Kyrgyzstan is a member of the Eurasian Economic Union (EAEU) and follows the EAEU medical device regulatory framework. Devices with EAEU registration are recognized across all member states including Kyrgyzstan.	SOMETIMES
Laos	PARTIAL	The Food and Drug Department (FDD) under Laos's Ministry of Health regulates medical devices as part of the ASEAN framework. Registration typically requires evidence of approval from the country of origin. Regulatory capacity is still developing and formal reliance is limited.	YES
Latvia	YES	Latvia is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The State Agency of Medicines (ZVA) oversees implementation.	NO



Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
Malaysia	PARTIAL	The Medical Device Authority (MDA) regulates medical devices in Malaysia under the Medical Device Act 2012. Malaysia participates in the ASEAN harmonization framework. Foreign regulatory approvals are considered, but a national registration process is required. ASEAN harmonization has enabled some reliance among ASEAN member states.	YES
Maldives	PARTIAL	The Maldives Food and Drug Authority (MFDA) regulates health products including medical devices. Given the small regulatory capacity, foreign approvals (WHO, FDA, CE) are typically required as the primary basis for registration. A formal structured reliance pathway is still developing.	YES
Malta	YES	Malta is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Medicines Authority oversees implementation. CE marking is the required pathway.	NO
Mauritius	PARTIAL	The Ministry of Health in Mauritius regulates medical devices. International regulatory approvals (FDA, CE, WHO) are typically required as supporting evidence for registration. A formal structured reliance pathway is not fully established.	YES
Mexico	YES	COFEPRIS (Federal Commission for Protection against Sanitary Risk) has a reliance pathway that accepts prior approvals from recognized regulatory authorities (FDA, CE, Health Canada, ANVISA) to expedite medical device registration in Mexico. This significantly reduces the review time for devices with established international approvals.	YES
Moldova	PARTIAL	The Agency for Medicines and Medical Devices of Moldova (AMDM) regulates medical devices. Moldova has signed an Association Agreement with the EU and is progressively aligning with EU standards. CE marking is recognized as supporting evidence but a national registration process is maintained.	SOMETIMES
Mongolia	PARTIAL	Mongolia's Ministry of Health regulates medical devices through the Pharmaceutical and Medical Device Control Department. Foreign regulatory approvals (FDA, CE) are accepted as supporting documentation for registration. A formal structured reliance pathway is limited.	YES
Montenegro	PARTIAL	The Agency for Medicines and Medical Devices of Montenegro (CALIMS) regulates medical devices. As an EU candidate country, Montenegro is aligning with EU MDR/IVDR. CE marking is generally recognized, but a national registration process is still required.	SOMETIMES
Morocco	PARTIAL	Morocco's Ministry of Health (Direction du Médicament et de la Pharmacie) regulates medical devices. Foreign regulatory approvals (FDA, CE) are typically required as part of the registration dossier. Morocco is progressing toward greater alignment with international standards.	YES
Myanmar	PARTIAL	The Food and Drug Administration of Myanmar (MFDA) regulates medical devices as part of the ASEAN framework. Registration typically requires evidence of approval from the country of origin. Regulatory capacity is still developing and the formal reliance framework is limited.	YES
Namibia	PARTIAL	The Namibia Medicines Regulatory Council (NMRC) regulates health products including medical devices. International regulatory approvals are accepted as supporting documentation. Regulatory capacity is developing and formal reliance is limited.	YES
Netherlands	YES	The Netherlands is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Health and Youth Care Inspectorate (IGJ) oversees compliance. CE marking is the required pathway.	NO
New Zealand	YES	Medsafe (New Zealand Medicines and Medical Devices Safety Authority) has a reliance pathway for medical devices that accepts approvals from comparable overseas regulators including TGA (Australia), FDA, and EMA. New Zealand also participates in a joint therapeutic products framework with Australia.	SOMETIMES
		The Ministry of Health (MINSa) through its Center for Sanitary Licensing (CNDR)	

Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
Pakistan	PARTIAL	The Drug Regulatory Authority of Pakistan (DRAP) regulates medical devices under the Medical Devices Rules 2017. Foreign regulatory approvals (FDA, CE, WHO) are required as part of the registration dossier. A formal structured reliance pathway is still being developed.	YES
Palestine	UNKNOWN	The Palestinian Authority Ministry of Health has very limited regulatory capacity for medical devices. No formal medical device reliance pathway has been established due to the complex political and administrative situation.	UNKNOWN
Panama	PARTIAL	The Ministry of Health (Minsa) and the CSS regulate medical devices in Panama. Foreign regulatory approvals are accepted as supporting documentation. Panama has adopted some regional harmonization approaches from PANDRH but formal structured reliance is limited.	YES
Paraguay	PARTIAL	The National Health Surveillance Directorate (DINAVISa) under Paraguay's Ministry of Health regulates medical devices. Foreign regulatory approvals (FDA, ANVISA, CE) are accepted as supporting documentation. A formal structured reliance pathway is in development.	YES
Peru	YES	DIGEMID (Dirección General de Medicamentos, Insumos y Drogas) has a reliance pathway that accepts prior approvals from recognized regulatory authorities (FDA, CE, ANVISA, Health Canada, INVIMA) to expedite medical device registration in Peru. Devices with established international approvals receive an expedited review.	YES
Philippines	PARTIAL	The FDA Philippines regulates medical devices as part of the ASEAN harmonization framework. Foreign regulatory approvals from recognized agencies are considered in the registration process. The Philippines FDA has provisions for recognized benchmark regulators, but a national registration is still required.	YES
Poland	YES	Poland is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products (URPL) oversees implementation. CE marking is the required pathway.	NO
Portugal	YES	Portugal is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). INFARMED (National Authority of Medicines and Health Products) oversees implementation. CE marking is the required pathway.	NO
Puerto Rico	YES	Puerto Rico is a US territory and falls under US FDA jurisdiction for medical device regulation. The same FDA 510(k), PMA, and De Novo pathways that apply to mainland US apply to Puerto Rico. No separate registration is required for devices already FDA-cleared or approved.	NO
Qatar	YES	Qatar's Ministry of Public Health participates in the GCC harmonized medical device registration framework. The Medical Devices Registration Department accepts FDA/CE approvals as the basis for registration. Qatar also has its own national registration system that accepts internationally approved devices.	YES
Republic of Serbia	PARTIAL	The Agency for Medicines and Medical Devices of Serbia (ALIMS) regulates medical devices. As an EU candidate country, Serbia is progressively aligning with EU MDR/IVDR. CE marking is recognized as important supporting evidence, but a national registration process is currently maintained.	SOMETIMES
Romania	YES	Romania is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The National Agency for Medicines and Medical Devices (ANMDMR) oversees implementation. CE marking is the required pathway.	NO
Russia	PARTIAL	Roszdravnadzor regulates medical devices in Russia. Russia is a member of the EAEU and the EAEU medical device regulations provide a framework for intra-union recognition. However, Russia maintains its own national registration system and has limited reliance on non-EAEU foreign approvals.	SOMETIMES
		The Rwanda Food and Drugs Authority (RFDA) regulates medical devices and	



Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
Slovenia	YES	Slovenia is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Agency for Medicinal Products and Medical Devices (JAZMP) oversees implementation. CE marking is the required pathway.	NO
South Africa	YES	The South African Health Products Regulatory Authority (SAHPRA) has a reliance pathway for medical devices that accepts prior approvals from recognized regulatory authorities (FDA, EMA, TGA, Health Canada) to expedite registration. SAHPRA's medical device regulatory framework explicitly supports reliance-based approaches.	YES
South Korea	PARTIAL	Korea's Ministry of Food and Drug Safety (MFDS) regulates medical devices under the Medical Devices Act. MFDS participates in MDSAP and has some provisions for expedited review for devices approved by recognized regulators (FDA, EMA). However, Korea generally conducts its own independent technical reviews and may require Korean clinical data.	SOMETIMES
Spain	YES	Spain is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Spanish Agency of Medicines and Medical Devices (AEMPS) oversees implementation. CE marking is the required pathway.	NO
Sri Lanka	PARTIAL	The National Medicines Regulatory Authority (NMRA) in Sri Lanka regulates medical devices. Foreign regulatory approvals (FDA, CE, WHO) are accepted as supporting documentation in registration dossiers. A formal structured reliance pathway is in development.	YES
Sudan	UNKNOWN	The Federal Ministry of Health in Sudan has very limited regulatory capacity for medical devices. The ongoing political and conflict situation further limits regulatory function. No formal reliance pathway for medical devices has been established.	UNKNOWN
Suriname	UNKNOWN	Suriname's Ministry of Health regulates health products but has very limited regulatory capacity for medical devices. No formal reliance pathway for medical devices has been established.	UNKNOWN
Sweden	YES	Sweden is an EU Member State and follows EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). The Medical Products Agency (MPA/LMV) oversees implementation and vigilance. CE marking is the required pathway.	NO
Switzerland	YES	Swissmedic regulates medical devices and Switzerland has a Mutual Recognition Agreement (MRA) with the EU. CE marking is accepted under the MRA framework. Switzerland has updated its Medical Devices Ordinance to align with EU MDR/IVDR, enabling smooth recognition of EU-approved devices.	SOMETIMES
Syria	UNKNOWN	Syria's Ministry of Health has very limited regulatory capacity for medical devices due to the ongoing conflict situation. No formal reliance pathway for medical devices has been established or can be reliably assessed.	UNKNOWN
Taiwan	PARTIAL	Taiwan's TFDA (Taiwan Food and Drug Administration) regulates medical devices. For certain device classes, TFDA accepts prior approvals from recognized regulatory authorities (FDA, CE, PMDA) to expedite registration. The level of reliance varies by device classification and risk level.	SOMETIMES
Tanzania	PARTIAL	The Tanzania Medicines and Medical Devices Authority (TMDA) regulates medical devices and participates in the EAC harmonization program. International regulatory approvals (WHO, FDA, EMA) are accepted as supporting evidence. TMDA is building regulatory capacity toward a more formal reliance framework.	YES
Thailand	PARTIAL	The FDA of Thailand regulates medical devices as part of the ASEAN harmonization framework. Foreign regulatory approvals from recognized agencies are considered in the registration process. Thailand has provisions for reliance on internationally approved devices, with expedited pathways for certain device categories.	YES
Tunisia	PARTIAL	Tunisia's Directorate of Pharmacy and Medicines under the Ministry of Health regulates medical devices. Foreign regulatory approvals (FDA, CE) are typically required as part of the registration dossier. A formal structured reliance pathway is limited.	YES



Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
United Arab Emirates	YES	The UAE has multiple regulatory authorities including the Ministry of Health and Prevention (MOHAP), Dubai Health Authority (DHA), and Department of Health Abu Dhabi (DOH). The UAE accepts FDA/CE approvals as the basis for registration and participates in the GCC harmonized framework. Each emirate has its own registration process but reliance on international approvals is well-established.	YES
United Kingdom	YES	Post-Brexit, the MHRA (Medicines and Healthcare products Regulatory Agency) has implemented the UKCA (UK Conformity Assessed) marking requirement. The MHRA has an International Reliance Route that allows manufacturers to use approvals from recognized international regulators (FDA, EMA, TGA, Health Canada) to support UKCA applications. CE marking was accepted transitionally through a phased period.	SOMETIMES
United States of America	PARTIAL	The FDA's Center for Devices and Radiological Health (CDRH) generally conducts independent technical reviews for 510(k), PMA, and De Novo submissions. The FDA participates in MDSAP which enables reliance on shared audit reports. The FDA has bilateral agreements and MOUs with select regulators but does not broadly rely on foreign regulatory decisions as the sole basis for approval.	NO
Uruguay	PARTIAL	The Ministry of Public Health (MSP) through its National Health Resource Unit regulates medical devices in Uruguay. Foreign regulatory approvals (FDA, ANVISA, CE, ANMAT) are accepted as supporting documentation. A formal structured reliance pathway is in development.	YES
Venezuela	PARTIAL	The National Institute of Hygiene Rafael Rangel (INHRR) regulates medical devices in Venezuela. The political and economic situation has significantly impacted regulatory capacity. Foreign regulatory approvals are typically required as part of the registration dossier but formal reliance is limited.	YES
Vietnam	PARTIAL	The Drug Administration of Vietnam (DAV) regulates medical devices as part of the ASEAN harmonization framework. Vietnam's Circular 36/2016/TT-BYT and subsequent regulations allow for reliance on approvals from recognized regulatory authorities (FDA, CE) for certain device categories, expediting the registration process.	YES
Yemen	UNKNOWN	Yemen's Ministry of Health has very limited regulatory capacity due to the ongoing conflict situation. No formal reliance pathway for medical devices has been established or can be reliably assessed.	UNKNOWN
Zimbabwe	PARTIAL	The Medicines Control Authority of Zimbabwe (MCAZ) regulates medical devices and has provisions for accepting internationally approved products as the basis for expedited registration. International regulatory approvals (WHO, FDA, EMA) are accepted as supporting evidence in registration dossiers.	YES

Regional Bodies — Special Chapter

The following 12 entries represent supranational or regional regulatory frameworks rather than individual sovereign nations. These include ASEAN, the European Union, GCC/Gulf Region, African regional bodies, and other multi-country frameworks. Individual member states within each framework may have additional national requirements beyond the regional baseline.

Country / Region	Pathway Exists?	Pathway Description	FSC / CGF Required?
ASEAN (Regional)	PARTIAL	ASEAN has the ASEAN Medical Device Directive (AMDD) harmonization framework encouraging member states to rely on each other's regulatory reviews. However, each member state still maintains its own national approval process. Reliance is encouraged but not formalized as a single binding pathway.	SOMETIMES
Africa (Regional)	PARTIAL	The African Medicines Regulatory Harmonisation (AMRH) initiative under the African Union is working toward regional harmonization of medical device regulations. The Africa CDC supports capacity building. A formal continent-wide reliance pathway does not yet exist but is under development.	UNKNOWN
Americas (Regional)	PARTIAL	PAHO (Pan American Health Organization) and PANDRH (Pan American Network for Drug Regulatory Harmonization) promote regulatory convergence across the Americas. No single binding reliance pathway exists, but harmonization frameworks are in development across the region.	UNKNOWN
Asia-Pacific (Regional)	PARTIAL	The Asia-Pacific Economic Cooperation (APEC) and the APEC Life Sciences Innovation Forum (LSIF) promote regulatory harmonization across the region. The Asia Pacific Medical Technology Association (APACMed) advocates for convergence. No binding single pathway exists across the entire region.	UNKNOWN
Caribbean (Regional)	PARTIAL	CARICOM (Caribbean Community) has initiated regional harmonization efforts for medicines and health products regulation. The Caribbean Regulatory System (CRS) is developing frameworks but medical device-specific reliance pathways are not yet fully formalized across the region.	UNKNOWN
East Africa (Regional)	PARTIAL	The East African Community (EAC) has been working on regulatory harmonization for medicines and medical devices through the EAC Medicines Regulatory Harmonisation Programme. Member states (Kenya, Uganda, Tanzania, Rwanda, Burundi, South Sudan) are progressively aligning their frameworks.	SOMETIMES
Europe (Regional)	YES	The European regulatory framework for medical devices is governed by EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746). CE marking through Notified Bodies is the single market pathway. EEA countries (Norway, Iceland, Liechtenstein) and Switzerland also participate in aligned frameworks.	NO
European Union	YES	The EU MDR (Regulation 2017/745) and IVDR (Regulation 2017/746) establish a harmonized regulatory framework for medical devices across all 27 EU member states. CE marking issued by an accredited Notified Body provides market access across the entire EU single market.	NO
Global	PARTIAL	The International Medical Device Regulators Forum (IMDRF) promotes global regulatory convergence and develops guidance documents to harmonize medical device regulations worldwide. IMDRF does not issue approvals but its frameworks (including the MDSAP audit program) enable reliance across member jurisdictions.	NO
Gulf Region (Regional)	PARTIAL	The Gulf Cooperation Council (GCC) has a harmonized medical device registration framework through the GCC Central Registration (GCC-CR) program. Member states (Saudi Arabia, UAE, Bahrain, Kuwait, Oman, Qatar) accept FDA/CE approvals as the basis for GCC registration. The GCC Technical Regulation aligns with GHTF/IMDRF principles.	SOMETIMES
International	PARTIAL	International refers to global harmonization bodies such as IMDRF, ISO, and IEC. These organizations develop standards and guidance documents that national regulators use as the basis for their regulatory frameworks, enabling convergence and mutual recognition without issuing approvals directly.	UNKNOWN
		There is no single Middle East-wide regulatory body for medical devices. GCC countries	