



# Reliance Pathway Report

Global Medical Device Regulatory Reliance Analysis

**131**

Countries & Regions Analyzed

**120**

Have Reliance Pathway

**8**

Partial / Developing

**3**

No Formal Pathway

Research based on IMDRF frameworks, official regulatory authority publications, and RegDesk regulatory intelligence

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## Executive Summary

This report analyzes the regulatory reliance pathway status for **131 countries and regional bodies** served by RegDesk. A reliance pathway allows national regulatory authorities to leverage prior assessments by recognized foreign regulators (such as FDA, EMA, TGA, Health Canada, PMDA) to expedite domestic market authorization for medical devices.

The analysis is guided by the **IMDRF N67:2019 framework** on "Regulatory Reliance Principles" and covers three key questions: (1) existence of a reliance pathway, (2) pathway description, and (3) FSC/Certificate of Good Standing requirements.

**120**

Countries with formal reliance pathway (YES)

**8**

Countries with partial/developing pathway

**3**

Countries with no formal pathway

**131**

Total countries & regions analyzed

## Key Findings

- **91.6%** of sovereign countries covered by RegDesk have formal reliance pathways in place
- **EU/EEA member states** (27 EU + Norway, Liechtenstein) operate under EU MDR/IVDR — CE marking is the sole basis for market access
- **EAEU countries** (Russia, Kazakhstan, Belarus, Armenia, Kyrgyzstan) operate under a unified technical regulation framework
- **GCC countries** (Saudi Arabia, UAE, Kuwait, Qatar, Bahrain, Oman) share a harmonized framework recognizing CE and FDA as primary references
- **China** stands out as not having a general reliance pathway — full NMPA registration with local clinical data is required
- **Hong Kong** operates a voluntary listing scheme with no mandatory registration, making reliance inapplicable
- **FSC (Free Sale Certificate)** is required in the majority (~72) of non-EU/EEA countries, particularly in Asia, Africa, Latin America, and Middle East

## Methodology

Data sourced from: IMDRF published guidance documents, official regulatory authority websites, RegDesk regulatory intelligence database, WHO prequalification frameworks, and regional harmonization body publications (GCC MDRAC, ASEAN AMDD, EAC RRHSS, PANDRH, ECOWAS, AU/AMA). Pathway status reflects the framework as of Q2 2025. Regulatory requirements are subject to change — always verify with official sources.



## Reliance Pathway Data — Country Index (A–Z)

| Country                | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                                                 | Q3: FSC Required? |
|------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Albania                | YES                 | Albania aligns with EU MDR/IVDR frameworks as part of its EU accession process. CE marking is recognized and used as basis for reliance/approval. The regulatory authority (AKMF) accepts CE-marked devices with Notified Body certificates.                                                                            | REQUIRED          |
| Algeria                | YES                 | Algeria's Ministry of Health requires registration of medical devices. Reliance on CE marking and/or FDA approval is accepted as supporting documentation, but a full national registration is still required. The LNCPP (national lab) may perform additional review.                                                  | REQUIRED          |
| Argentina              | YES                 | ANMAT (Argentina) operates a formal reliance pathway. Devices approved by FDA, EMA, Health Canada, TGA, or other IMDRF-recognized authorities may be eligible for an abbreviated review process. Class III devices may require full dossier; lower-class devices can use reliance.                                      | REQUIRED          |
| Armenia                | YES                 | Armenia is part of the Eurasian Economic Union (EAEU). Medical devices must comply with EAEU Technical Regulations (TR EAEU 017/2011). Reliance is based on EAEU harmonized framework; certificates of conformity issued by EAEU-recognized certification bodies.                                                       | REQUIRED          |
| Australia              | YES                 | TGA (Therapeutic Goods Administration) has a formal reliance pathway. For Class III and AIMD devices, TGA may rely on EU Notified Body conformity assessments. The MDSAP (Medical Device Single Audit Program) is also accepted. Streamlined pathways exist for devices approved by comparable regulators.              | NOT REQUIRED      |
| Austria                | YES                 | Austria follows EU MDR (2017/745) and IVDR (2017/746) directly as an EU member state. CE marking with Notified Body certification is the approval basis. No separate national reliance pathway needed beyond CE mark.                                                                                                   | NOT REQUIRED      |
| Azerbaijan             | YES                 | Azerbaijan requires registration of medical devices through the Ministry of Health. CE marking or other recognized international approvals may support the registration dossier, but full national registration is required.                                                                                            | REQUIRED          |
| Bahrain                | YES                 | NHRA (National Health Regulatory Authority) of Bahrain accepts CE marking and FDA 510(k)/PMA as supporting documentation for registration. Gulf Cooperation Council (GCC) harmonization initiatives also apply. A formal reliance pathway is in place for recognized authority approvals.                               | REQUIRED          |
| Bangladesh             | YES                 | DGDA (Directorate General of Drug Administration) regulates medical devices. Reliance on WHO prequalification, CE marking, or FDA approval is used as supporting documentation. Full registration with DGDA is required; reliance reduces dossier requirements.                                                         | REQUIRED          |
| Belarus                | YES                 | Belarus is part of the EAEU framework. Medical devices must comply with EAEU Technical Regulations. Registration via EAEU unified system with state registration certificates required.                                                                                                                                 | REQUIRED          |
| Belgium                | YES                 | Belgium follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. FAMHP (Federal Agency for Medicines and Health Products) oversees compliance.                                                                                                                                             | NOT REQUIRED      |
| Bolivia                | YES                 | AGEMED (Bolivia) regulates medical devices. Registration is required; reliance on FDA, CE, or recognized regional authority approvals may support a simplified review. Bolivia participates in PANDRH harmonization network.                                                                                            | REQUIRED          |
| Bosnia and Herzegovina | YES                 | Bosnia and Herzegovina aligns medical device regulations with EU MDR framework as part of EU stabilization process. CE marking is the primary reference for device approval. The Agency for Medicinal Products and Medical Devices (ALIMS) oversees registration.                                                       | REQUIRED          |
| Brazil                 | YES                 | ANVISA (Brazil) has a formal reliance pathway. Devices from countries with recognized regulatory authorities (Category I countries: USA, EU, Canada, Japan, Australia) are eligible for priority/abbreviated review. Category I devices can receive faster registration using the foreign approval as primary evidence. | REQUIRED          |



## Reliance Pathway Data — Country Index (A–Z)

| Country            | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                            | Q3: FSC Required? |
|--------------------|---------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Bulgaria           | YES                 | Bulgaria follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. BDA (Bulgarian Drug Agency) oversees compliance.                                                                                                                                                    | NOT REQUIRED      |
| Cambodia           | YES                 | MAFF/Ministry of Health regulates medical devices in Cambodia. Reliance on CE marking, FDA, TGA, or PMDA approvals is accepted to support registration. Cambodia is part of ASEAN harmonization efforts.                                                                                           | REQUIRED          |
| Canada             | YES                 | Health Canada has a formal reliance pathway called the 'Reliance on Foreign Reviews' program. For Class III and IV devices, Health Canada may rely on reviews completed by trusted partners (FDA, EMA, TGA, UK MHRA, etc.) under bilateral arrangements. Abbreviated submissions are accepted.     | NOT REQUIRED      |
| Chile              | YES                 | ISP (Instituto de Salud Pública) regulates medical devices in Chile. A formal reliance pathway exists for devices approved by FDA, EMA, Health Canada, TGA, or other recognized authorities. Class III devices (high-risk) may get expedited review based on foreign approval.                     | REQUIRED          |
| Colombia           | YES                 | INVIMA (Colombia) has a formal reliance pathway. Devices approved by health authorities of countries where the manufacturer is domiciled (Category A: EU, USA, Canada, Japan, Australia) receive a simplified registration process. Category A devices can be registered with abbreviated dossier. | REQUIRED          |
| Costa Rica         | YES                 | DNFD (Dirección Nacional de Farmacovigilancia y Dispositivos) in Costa Rica. Reliance on FDA, CE, or other recognized approvals is used for medical device registration. COMISCA/SIECA Central American regulatory harmonization is being developed.                                               | REQUIRED          |
| Croatia            | YES                 | Croatia follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. HALMED (Agency for Medicinal Products and Medical Devices) oversees compliance.                                                                                                                      | NOT REQUIRED      |
| Cuba               | YES                 | CECMED regulates medical devices in Cuba. Registration is required; reliance on WHO prequalification or recognized international approvals may support the dossier. Full national registration process applies.                                                                                    | REQUIRED          |
| Cyprus             | YES                 | Cyprus follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access.                                                                                                                                                                                                       | NOT REQUIRED      |
| Czech Republic     | YES                 | Czech Republic follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. SÚKL (State Institute for Drug Control) oversees compliance.                                                                                                                                  | NOT REQUIRED      |
| Denmark            | YES                 | Denmark follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. DKMA (Danish Medicines Agency) oversees compliance.                                                                                                                                                  | NOT REQUIRED      |
| Dominican Republic | YES                 | SESPAS/DIGEMAPS regulates medical devices in the Dominican Republic. Reliance on FDA, CE, or other recognized international approvals is used to support registration. Participation in PANDRH harmonization network.                                                                              | REQUIRED          |
| Ecuador            | YES                 | ARCSA (Ecuador) regulates medical devices. Reliance on FDA, CE, Health Canada, TGA, or other recognized authority approvals is accepted for a simplified registration process. Ecuador participates in PANDRH harmonization.                                                                       | REQUIRED          |
| Egypt              | YES                 | EGMED (Egyptian Drug Authority - medical devices division) requires registration. CE marking and FDA approval are used as supporting documentation. A reliance framework exists where recognized foreign approvals support abbreviated review. Egyptian registration is still mandatory.           | REQUIRED          |



## Reliance Pathway Data — Country Index (A–Z)

| Country     | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                                                                                      | Q3: FSC Required? |
|-------------|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| El Salvador | YES                 | CSSP/DNM (Dirección Nacional de Medicamentos) regulates medical devices. Reliance on FDA, CE, or other recognized approvals supports registration. Part of Central American regulatory harmonization initiatives.                                                                                                                                            | REQUIRED          |
| Estonia     | YES                 | Estonia follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. State Agency of Medicines oversees compliance.                                                                                                                                                                                                                 | NOT REQUIRED      |
| Ethiopia    | YES                 | EFDA (Ethiopian Food and Drug Authority) regulates medical devices. Reliance on WHO prequalification, CE marking, or FDA approval is used to support abbreviated review. National registration is required but WHO/CE-based reliance reduces dossier.                                                                                                        | REQUIRED          |
| Finland     | YES                 | Finland follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. Fimea (Finnish Medicines Agency) oversees compliance.                                                                                                                                                                                                          | NOT REQUIRED      |
| France      | YES                 | France follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. ANSM (Agence Nationale de Sécurité du Médicament) oversees compliance.                                                                                                                                                                                          | NOT REQUIRED      |
| Georgia     | YES                 | Georgia's LMPA (Lekartsvnebis Regulirebis Saagentso) regulates medical devices. As part of EU Association Agreement, Georgia aligns with EU standards. CE marking and recognized international approvals support registration.                                                                                                                               | REQUIRED          |
| Germany     | YES                 | Germany follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. BfArM (Federal Institute for Drugs and Medical Devices) oversees compliance.                                                                                                                                                                                   | NOT REQUIRED      |
| Ghana       | YES                 | FDA Ghana (Food and Drugs Authority) regulates medical devices. Reliance on WHO prequalification, CE marking, or FDA approval supports registration. Full national registration is required but recognized approvals expedite review.                                                                                                                        | REQUIRED          |
| Greece      | YES                 | Greece follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. EOF (National Organization for Medicines) oversees compliance.                                                                                                                                                                                                  | NOT REQUIRED      |
| Guatemala   | YES                 | MSPAS/DRCA (Departamento de Regulación y Control de Alimentos) regulates medical devices in Guatemala. Reliance on FDA, CE, or other recognized approvals supports registration. Central American harmonization (COMISCA) in progress.                                                                                                                       | REQUIRED          |
| Honduras    | YES                 | ARSA (Agencia de Regulación Sanitaria) regulates medical devices. Reliance on FDA, CE, or other recognized approvals is used for registration. Honduras participates in Central American harmonization efforts.                                                                                                                                              | REQUIRED          |
| Hungary     | YES                 | Hungary follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. OGYÉI (National Institute of Pharmacy and Nutrition) oversees compliance.                                                                                                                                                                                      | NOT REQUIRED      |
| India       | YES                 | CDSCO (Central Drugs Standard Control Organisation) has a reliance pathway under the Medical Devices Rules 2017. For Class C and D devices, CDSCO may grant approval based on approval from a 'Recognized Foreign Regulatory Authority' (RFRA) such as FDA, EMA, TGA, Health Canada, or Japan PMDA. The RFRA pathway significantly reduces review timelines. | REQUIRED          |
| Indonesia   | YES                 | BPOM (Badan Pengawas Obat dan Makanan) regulates medical devices. Reliance on CE marking, FDA, TGA, or PMDA approvals is accepted as supporting evidence. Indonesia participates in ASEAN harmonization. Full BPOM registration is required but recognized approvals reduce the dossier burden.                                                              | REQUIRED          |



## Reliance Pathway Data — Country Index (A–Z)

| Country    | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                                                                                                     | Q3: FSC Required? |
|------------|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Iran       | YES                 | IMED (Iran Medical Device Directorate) under the Ministry of Health regulates devices. Registration is required. CE marking may be referenced as supporting documentation but is not always sufficient alone. Full Iranian registration process applies.                                                                                                                    | REQUIRED          |
| Iraq       | YES                 | Iraq's Ministry of Health (KIMADIA) regulates medical devices through procurement and registration. CE marking and recognized international approvals are typically required as supporting documentation. Formal reliance framework is developing.                                                                                                                          | REQUIRED          |
| Ireland    | YES                 | Ireland follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. HPRA (Health Products Regulatory Authority) oversees compliance.                                                                                                                                                                                                              | NOT REQUIRED      |
| Israel     | YES                 | AMAR (Medical Device and Drug Administration, Ministry of Health Israel) has a formal reliance pathway. Israel recognizes FDA, EMA/CE, Health Canada, TGA, and other IMDRF member approvals. Class II and III devices can obtain registration via reliance on a primary approval from a recognized authority.                                                               | NOT REQUIRED      |
| Italy      | YES                 | Italy follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. AIFA and Ministry of Health oversee compliance.                                                                                                                                                                                                                                 | NOT REQUIRED      |
| Japan      | YES                 | PMDA (Pharmaceuticals and Medical Devices Agency) regulates medical devices. Japan has a foreign manufacturing accreditation system and recognition of overseas manufacturing sites. A partial reliance framework exists: for certain devices, prior approval by FDA or EMA may reduce clinical data requirements. The SAKIGAKE (priority review) designation also applies. | REQUIRED          |
| Jordan     | YES                 | JFDA (Jordan Food and Drug Administration) has a reliance pathway. CE marking and FDA approval are recognized as primary supporting evidence for registration. Jordan has one of the more advanced reliance frameworks in the Middle East.                                                                                                                                  | REQUIRED          |
| Kazakhstan | YES                 | Kazakhstan is part of the EAEU framework. Medical devices must comply with EAEU Technical Regulations (TR EAEU 017/2011). Registration via the EAEU unified system with state registration certificates.                                                                                                                                                                    | REQUIRED          |
| Kenya      | YES                 | KEBS/PPB (now PCEA - Pharmacy and Poisons Control Authority) regulates medical devices. Reliance on WHO prequalification, CE marking, or FDA/TGA approvals supports abbreviated registration. Kenya participates in EAC harmonization.                                                                                                                                      | REQUIRED          |
| Kosovo     | YES                 | Kosovo aligns medical device regulations with EU MDR as part of EU integration process. CE marking is the primary reference. AMMK (Agency for Medicines and Medical Devices) oversees registration.                                                                                                                                                                         | REQUIRED          |
| Kuwait     | YES                 | MOH Kuwait (Ministry of Health) regulates medical devices. Part of GCC harmonized framework. CE marking and FDA approval are accepted as primary supporting evidence for registration.                                                                                                                                                                                      | REQUIRED          |
| Kyrgyzstan | YES                 | Kyrgyzstan is part of the EAEU framework. Medical devices comply with EAEU Technical Regulations. State registration required via EAEU harmonized system.                                                                                                                                                                                                                   | REQUIRED          |
| Laos       | YES                 | Department of Food and Drug (DFD) regulates medical devices in Laos. Reliance on CE marking, WHO prequalification, or other ASEAN country approvals is accepted. Part of ASEAN harmonization efforts.                                                                                                                                                                       | REQUIRED          |
| Latvia     | YES                 | Latvia follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. SAM (State Agency of Medicines) oversees compliance.                                                                                                                                                                                                                           | NOT REQUIRED      |



## Reliance Pathway Data — Country Index (A–Z)

| Country       | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                     | Q3: FSC Required? |
|---------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Lebanon       | YES                 | Ministry of Public Health Lebanon regulates medical devices. CE marking and FDA approval are used as supporting documentation for registration. A reliance framework is in place where recognized approvals support abbreviated review.                                                     | REQUIRED          |
| Libya         | YES                 | NCDC/Ministry of Health Libya regulates devices. Reliance on CE marking or other recognized international approvals is used as supporting evidence. Regulatory environment is challenging due to political instability.                                                                     | REQUIRED          |
| Liechtenstein | YES                 | Liechtenstein follows EU MDR/IVDR through its EEA membership. CE marking is the basis for market access, equivalent to EU member states.                                                                                                                                                    | NOT REQUIRED      |
| Lithuania     | YES                 | Lithuania follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. VVKT (State Medicines Control Agency) oversees compliance.                                                                                                                                  | NOT REQUIRED      |
| Luxembourg    | YES                 | Luxembourg follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. Ministère de la Santé oversees compliance.                                                                                                                                                 | NOT REQUIRED      |
| Malaysia      | YES                 | MDA (Medical Device Authority) Malaysia has a formal reliance pathway. Under the Medical Device Act 2012, Class C and D devices from manufacturers approved by MDSAP-participating authorities or recognized foreign authorities (FDA, TGA, CE, PMDA) can apply for expedited registration. | NOT REQUIRED      |
| Malta         | YES                 | Malta follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. ADM (Medicines Authority) oversees compliance.                                                                                                                                                  | NOT REQUIRED      |
| Mexico        | YES                 | COFEPRIS (Mexico) has a formal reliance pathway. Devices approved by recognized health authorities (FDA, EMA, Health Canada, TGA) are eligible for a 'Third Party Reference' process (tercero autorizado). Expedited review is granted for devices with recognized foreign approvals.       | REQUIRED          |
| Moldova       | YES                 | Moldova aligns with EU MDR as part of EU Association Agreement. CE marking is accepted as primary reference for registration. AMDM (Agency for Medicines and Medical Devices) oversees compliance.                                                                                          | REQUIRED          |
| Montenegro    | YES                 | Montenegro aligns with EU MDR as part of EU accession process. CE marking is the primary reference. CALIMS (Agency for Medicines and Medical Devices) oversees registration.                                                                                                                | REQUIRED          |
| Morocco       | YES                 | Ministry of Health Morocco (DMCM) regulates medical devices. CE marking is the primary reference for device registration. A reliance-based approach is used where CE-certified devices receive expedited review.                                                                            | REQUIRED          |
| Mozambique    | YES                 | DNAM (Direcção Nacional de Assistência Médica) regulates medical devices. Reliance on WHO prequalification, CE marking, or other recognized approvals supports registration. Formal framework is developing.                                                                                | REQUIRED          |
| Myanmar       | YES                 | FDA Myanmar (Food and Drug Administration) regulates medical devices. CE marking, FDA, or TGA approvals are accepted as supporting documentation. Myanmar participates in ASEAN harmonization efforts.                                                                                      | REQUIRED          |
| Netherlands   | YES                 | Netherlands follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. CIBG (CBG-MEB) and IGJ oversee compliance.                                                                                                                                                | NOT REQUIRED      |



## Reliance Pathway Data — Country Index (A–Z)

| Country         | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                 | Q3: FSC Required? |
|-----------------|---------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| New Zealand     | YES                 | Medsafe (NZ) has a formal reliance pathway aligned with Australia's TGA. ANZTPA (Australia New Zealand Therapeutic Products Agency) joint regulatory framework is under development. New Zealand currently relies on TGA assessments for some devices and recognizes CE, FDA approvals. | NOT REQUIRED      |
| Nicaragua       | YES                 | MINSa Nicaragua (Ministry of Health) regulates medical devices. Reliance on FDA, CE, or other recognized approvals supports registration. Central American harmonization (COMISCA) efforts apply.                                                                                       | REQUIRED          |
| Nigeria         | YES                 | NAFDAC (National Agency for Food and Drug Administration and Control) regulates medical devices. Reliance on WHO prequalification, CE marking, or FDA approval supports abbreviated registration. Full NAFDAC registration is required but recognized approvals expedite the process.   | REQUIRED          |
| North Macedonia | YES                 | North Macedonia aligns with EU MDR as part of EU accession process. CE marking is the primary reference. MALMED (Medicines and Medical Devices Agency) oversees registration.                                                                                                           | REQUIRED          |
| Norway          | YES                 | Norway follows EU MDR/IVDR through its EEA membership. CE marking is the basis for market access, equivalent to EU member states. Noma (Norwegian Medicines Agency) oversees compliance.                                                                                                | NOT REQUIRED      |
| Oman            | YES                 | MOH Oman (Ministry of Health) and OAMD (Oman Authority for Medical Devices) regulate devices. Part of GCC harmonized framework. CE marking and FDA approval are accepted as primary supporting evidence.                                                                                | REQUIRED          |
| Pakistan        | YES                 | DRAP (Drug Regulatory Authority of Pakistan) regulates medical devices under the Medical Devices Ordinance. A reliance pathway exists where devices approved by IMDRF-recognized authorities (FDA, EMA, TGA, Health Canada) are eligible for expedited registration.                    | REQUIRED          |
| Palestine       | YES                 | MOH Palestine regulates medical devices. CE marking and FDA approval are used as supporting documentation for import authorization. Formal regulatory framework is limited; CE-based reliance is common in practice.                                                                    | REQUIRED          |
| Panama          | YES                 | MINSa Panama (Dirección General de Salud Pública) regulates medical devices. Reliance on FDA, CE, or other recognized approvals is used for registration. Panama participates in PANDRH harmonization.                                                                                  | REQUIRED          |
| Paraguay        | YES                 | INAN (Instituto Nacional de Alimentación y Nutrición) and DINAVISa regulate medical devices. Reliance on FDA, CE, or ANMAT (Argentina) approvals supports registration. Paraguay participates in PANDRH.                                                                                | REQUIRED          |
| Peru            | YES                 | DIGEMID (Peru) regulates medical devices. A formal reliance pathway exists for devices approved by recognized foreign authorities (FDA, CE, Health Canada, TGA, ANMAT). Abbreviated registration process available for Class III devices with recognized foreign approval.              | REQUIRED          |
| Philippines     | YES                 | FDA Philippines (Food and Drug Administration) has a reliance pathway for medical devices. CE marking and FDA (USA) approval are accepted as primary evidence for registration. Class C and D devices from recognized regulatory authorities benefit from expedited review.             | REQUIRED          |
| Poland          | YES                 | Poland follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. URPL (Office for Registration of Medicinal Products) oversees compliance.                                                                                                                  | NOT REQUIRED      |
| Portugal        | YES                 | Portugal follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. INFARMED oversees compliance.                                                                                                                                                            | NOT REQUIRED      |



## Reliance Pathway Data — Country Index (A–Z)

| Country                      | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                                                         | Q3: FSC Required? |
|------------------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| <a href="#">Qatar</a>        | YES                 | MOPH Qatar (Ministry of Public Health) regulates medical devices. Part of GCC harmonized framework. CE marking and FDA approval are accepted as primary supporting evidence for registration.                                                                                                                                   | REQUIRED          |
| <a href="#">Romania</a>      | YES                 | Romania follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. ANMDMR (National Agency for Medicines and Medical Devices) oversees compliance.                                                                                                                                                   | NOT REQUIRED      |
| <a href="#">Russia</a>       | YES                 | Roszdrazhnadzor (Russia) requires full national registration. Russia does NOT accept CE marking or FDA approval as basis for reliance — full Russian registration with technical dossier and clinical data in Russian is required. EAEU framework applies for some categories.                                                  | REQUIRED          |
| <a href="#">Saudi Arabia</a> | YES                 | SFDA (Saudi Food and Drug Authority) has a formal reliance pathway. Saudi Arabia recognizes CE marking (EU MDR) and FDA clearance/approval as primary supporting evidence. Devices from IMDRF-recognized authorities are eligible for the SFDA reliance pathway with abbreviated submission requirements.                       | REQUIRED          |
| <a href="#">Senegal</a>      | YES                 | DPM (Direction de la Pharmacie et du Médicament) and DPML regulate medical devices. Reliance on WHO prequalification, CE marking, or other recognized approvals is used as supporting evidence. West African ECOWAS harmonization efforts apply.                                                                                | REQUIRED          |
| <a href="#">Serbia</a>       | YES                 | Serbia aligns with EU MDR as part of EU accession process. CE marking is the primary reference. ALIMs (Agency for Medicines and Medical Devices of Serbia) oversees registration.                                                                                                                                               | REQUIRED          |
| <a href="#">Singapore</a>    | YES                 | HSA (Health Sciences Authority) Singapore has a formal reliance pathway. Singapore recognizes IMDRF-founding member approvals (FDA, EMA, TGA, Health Canada, PMDA). Class C and D devices approved by a recognized authority can apply via HSA's 'Abridged' or 'Verification' pathways for expedited registration.              | NOT REQUIRED      |
| <a href="#">Slovakia</a>     | YES                 | Slovakia follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. ŠÚKL (State Institute for Drug Control) oversees compliance.                                                                                                                                                                     | NOT REQUIRED      |
| <a href="#">Slovenia</a>     | YES                 | Slovenia follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. JAZMP (Agency for Medicinal Products and Medical Devices) oversees compliance.                                                                                                                                                   | NOT REQUIRED      |
| <a href="#">South Africa</a> | YES                 | SAHPRA (South African Health Products Regulatory Authority) has a formal reliance pathway. Under the SAHPRA Regulatory Strategy, devices approved by WHO prequalified or IMDRF-recognized authorities are eligible for reliance-based registration. CE marking and FDA approval are the most commonly used reference approvals. | REQUIRED          |
| <a href="#">South Korea</a>  | YES                 | MFDS (Ministry of Food and Drug Safety) Korea has a reliance pathway. Devices approved by IMDRF-founding members (FDA, EMA, TGA, Health Canada) may benefit from abbreviated review. Korea is an IMDRF founding member and actively participates in IMDRF harmonization. Third-party review bodies are also recognized.         | REQUIRED          |
| <a href="#">Spain</a>        | YES                 | Spain follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. AEMPS (Spanish Agency for Medicines and Medical Devices) oversees compliance.                                                                                                                                                       | NOT REQUIRED      |
| <a href="#">Sri Lanka</a>    | YES                 | NMRA (National Medicines Regulatory Authority) Sri Lanka regulates medical devices. Reliance on CE marking, FDA, TGA, or WHO prequalification is accepted as supporting evidence. Full NMRA registration required but recognized approvals reduce dossier requirements.                                                         | REQUIRED          |
| <a href="#">Sudan</a>        | YES                 | SFDA Sudan (Sudan Food and Drug Control Authority) regulates medical devices. Reliance on WHO prequalification, CE marking, or other recognized approvals supports abbreviated registration.                                                                                                                                    | REQUIRED          |



## Reliance Pathway Data — Country Index (A–Z)

| Country              | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                                                                                                                     | Q3: FSC Required? |
|----------------------|---------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Sweden               | YES                 | Sweden follows EU MDR/IVDR as an EU member state. CE marking is the basis for market access. MPA (Medical Products Agency) oversees compliance.                                                                                                                                                                                                                                             | NOT REQUIRED      |
| Switzerland          | YES                 | Swissmedic has a reliance pathway. Switzerland-EU MRA (Mutual Recognition Agreement) was renegotiated under EU MDR — Swiss approved devices require Swissmedic registration but the process involves reliance on CE Notified Body conformity assessment. From 2024, new rules under revised MRA apply.                                                                                      | NOT REQUIRED      |
| Syria                | YES                 | Ministry of Health Syria regulates medical devices. CE marking or other recognized international approvals may be referenced as supporting documentation. Regulatory environment is severely impacted by ongoing conflict.                                                                                                                                                                  | REQUIRED          |
| Taiwan               | YES                 | TFDA (Taiwan Food and Drug Administration) has a reliance pathway. Taiwan recognizes FDA, CE/EMA approvals as primary supporting evidence for Class II and III devices. Expedited review is available for devices approved by FDA or EMA.                                                                                                                                                   | REQUIRED          |
| Tanzania             | YES                 | TMDA (Tanzania Medicines and Medical Devices Authority) regulates devices. Reliance on WHO prequalification, CE marking, or other recognized approvals supports registration. Part of EAC harmonization efforts.                                                                                                                                                                            | REQUIRED          |
| Thailand             | YES                 | FDA Thailand (Food and Drug Administration) has a reliance pathway. CE marking and FDA approvals are accepted as primary supporting evidence for Class III and higher-risk devices. Thailand participates in ASEAN Medical Device Directive harmonization.                                                                                                                                  | REQUIRED          |
| Tunisia              | YES                 | DPM Tunisia (Direction de la Pharmacie et du Médicament) regulates medical devices. CE marking is the primary reference for device registration, with a reliance-based approach for CE-certified devices.                                                                                                                                                                                   | REQUIRED          |
| Turkey               | YES                 | TİTCK (Turkish Medicines and Medical Devices Agency) has a formal reliance pathway. Turkey aligns with EU MDR/IVDR frameworks under the Customs Union agreement. CE marking is the primary basis for registration; devices with valid CE certificates from EU Notified Bodies receive streamlined Turkish registration.                                                                     | NOT REQUIRED      |
| Uganda               | YES                 | NDA Uganda (National Drug Authority) regulates medical devices. Reliance on WHO prequalification, CE marking, or other recognized approvals supports abbreviated registration. Part of EAC harmonization.                                                                                                                                                                                   | REQUIRED          |
| Ukraine              | YES                 | MOZ Ukraine (Ministry of Health) regulates medical devices. Ukraine aligns with EU MDR frameworks under the EU-Ukraine Association Agreement. CE marking is used as primary reference for state registration, particularly for Class IIa and higher devices.                                                                                                                                | REQUIRED          |
| United Arab Emirates | YES                 | MOHAP (Ministry of Health and Prevention UAE) and emirate-level authorities (Dubai Health Authority, DoH Abu Dhabi) regulate medical devices. Part of GCC framework. CE marking and FDA approval are widely accepted as primary evidence. MOHAP has a formal reliance pathway for IMDRF-recognized authority approvals.                                                                     | REQUIRED          |
| United Kingdom       | YES                 | MHRA (Medicines and Healthcare products Regulatory Agency) has a formal reliance pathway post-Brexit. UK Conformity Assessed (UKCA) mark is required for Great Britain; CE marking continues for Northern Ireland (Windsor Framework). MHRA has an 'International Recognition' pathway recognizing FDA, EMA/CE, Health Canada, TGA, and Japan PMDA approvals for expedited UK registration. | NOT REQUIRED      |
| United States        | YES                 | FDA (Food and Drug Administration) CDRH is itself a primary reference authority. FDA participates in IMDRF and has bilateral agreements (MDSAP, bilateral MRAs). FDA does not apply formal reliance on other authorities' approvals — it is the reference authority rather than a relying authority.                                                                                        | NOT REQUIRED      |
| Uruguay              | YES                 | MSP Uruguay (Ministerio de Salud Pública) / URSEA regulate medical devices. Reliance on FDA, CE, ANMAT (Argentina), or other recognized approvals is used for simplified registration. Uruguay participates in PANDRH harmonization.                                                                                                                                                        | REQUIRED          |



## Reliance Pathway Data — Country Index (A–Z)

| Country    | Q1: Pathway Exists? | Q2: Pathway Description                                                                                                                                                                                                                                                                        | Q3: FSC Required? |
|------------|---------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|
| Uzbekistan | YES                 | State Center of Medical Statistics of Uzbekistan / Ministry of Health regulates devices. Registration is required; CE marking or recognized international approvals may support the dossier. Framework is developing toward EAEU alignment.                                                    | REQUIRED          |
| Venezuela  | YES                 | INHRR (Instituto Nacional de Higiene Rafael Rangel) regulates medical devices. Reliance on FDA, CE, or other recognized approvals is used as supporting documentation. Regulatory environment has been impacted by political and economic instability.                                         | REQUIRED          |
| Vietnam    | YES                 | DAV (Drug Administration of Vietnam) under the Ministry of Health regulates medical devices. Reliance on CE marking, FDA, TGA, or PMDA approvals is accepted for Class C and D devices. Vietnam participates in ASEAN harmonization. CE/FDA approval reduces local clinical data requirements. | REQUIRED          |
| Yemen      | YES                 | Ministry of Public Health Yemen regulates medical devices. CE marking or other recognized international approvals are referenced as supporting documentation. Regulatory capacity is severely limited due to ongoing conflict.                                                                 | REQUIRED          |
| Zimbabwe   | YES                 | MCAZ (Medicines Control Authority of Zimbabwe) regulates medical devices. Reliance on WHO prequalification, CE marking, or other recognized approvals supports abbreviated registration.                                                                                                       | REQUIRED          |



## Special Chapter: Regional Bodies & Countries Without Full Reliance Criteria

The following entries represent **regional harmonization bodies** (which do not independently approve devices but set frameworks for member states) and **countries where no formal reliance pathway has been established** or the pathway is only partially developed. Manufacturers should assess member-state-level requirements individually.

| Country / Region        | Status  | Description / Notes                                                                                                                                                                                                                                                                                                                                          | FSC          |
|-------------------------|---------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| ASEAN (Regional)        | PARTIAL | ASEAN has a Medical Device Directive (AMDD) framework promoting harmonization. Individual ASEAN member states (e.g., Thailand, Vietnam, Malaysia) maintain national reliance pathways, some referencing FDA, CE, TGA, or PMDA approvals. No single unified ASEAN-wide reliance pathway exists yet.                                                           | VARIES       |
| Africa (Regional)       | PARTIAL | The African Union and African Medicines Agency (AMA) are developing continental harmonization frameworks. Some regional bodies (e.g., ECOWAS, SADC, EAC) have reliance discussions but no binding reliance pathway is operational continent-wide.                                                                                                            | VARIES       |
| Americas (Regional)     | PARTIAL | PAHO (Pan American Health Organization) supports regulatory convergence across the Americas through the PANDRH network. Individual countries maintain their own reliance frameworks.                                                                                                                                                                         | NOT REQUIRED |
| Asia-Pacific (Regional) | PARTIAL | APEC RHSC (Regulatory Harmonization Steering Committee) promotes reliance frameworks across Asia-Pacific. No binding regional reliance pathway; individual countries follow IMDRF guidelines.                                                                                                                                                                | NOT REQUIRED |
| Caribbean (Regional)    | PARTIAL | The Caribbean Community (CARICOM) has a Regional Organisation for Standards and Quality (CROSQ) that promotes harmonization. Individual CARICOM member states maintain their own medical device registration requirements, often relying on FDA or CE approvals.                                                                                             | NOT REQUIRED |
| East Africa (Regional)  | PARTIAL | The East African Community (EAC) has a harmonization framework for medicines and medical devices through EAC RRHSS. Individual member states (Kenya, Uganda, Tanzania, Rwanda, Burundi, South Sudan) maintain national registration requirements with growing reliance on recognized approvals.                                                              | NOT REQUIRED |
| Europe (Regional)       | YES     | The EU MDR (2017/745) and IVDR (2017/746) constitute the regional regulatory framework for EU member states. CE marking via Notified Body is the primary pathway. EUDAMED database is the central registry.                                                                                                                                                  | NOT REQUIRED |
| Global (Multi-region)   | PARTIAL | IMDRF (International Medical Device Regulators Forum) has established guidance on reliance (IMDRF/RWG/N67FINAL:2019). WHO also supports reliance frameworks for developing countries. These are guidance frameworks, not binding pathways.                                                                                                                   | NOT REQUIRED |
| Gulf Region (Regional)  | YES     | The Gulf Cooperation Council (GCC) has a harmonized medical device regulation through MDRAC (Medical Device Regulatory Affairs Committee). GCC Technical Regulation for Medical Devices requires registration via national competent authorities. CE marking and FDA approval are widely accepted as primary supporting evidence.                            | REQUIRED     |
| International (Global)  | PARTIAL | International bodies like IMDRF and WHO promote reliance frameworks globally. IMDRF N67 (2019) and N57 (2019) provide guidance on reliance and recognition pathways. Individual countries adopt these frameworks voluntarily.                                                                                                                                | NOT REQUIRED |
| Middle East (Regional)  | YES     | The GCC (Gulf Cooperation Council) represents the most developed regional framework. Arab regulatory harmonization through ARAO (Arab Regulators Organization) is also progressing. CE marking and FDA approval are the most widely recognized references in the region.                                                                                     | NOT REQUIRED |
| Afghanistan             | NO      | Afghanistan does not have an established formal medical device regulatory reliance pathway. The regulatory framework is nascent; the Ministry of Public Health oversees medical devices with limited formal review processes.                                                                                                                                | SEE NOTE     |
| China                   | NO      | China (NMPA) does not have a general reliance pathway. All medical devices require full NMPA registration with clinical data, technical dossier, and in many cases clinical trials conducted in China. Some exceptions exist for imported Class II devices in free trade zones. NMPA does not recognize foreign approvals as primary basis for registration. | REQUIRED     |
| Hong Kong               | NO      | Hong Kong does not have a mandatory medical device registration system. The MDCO (Medical Device Control Office) operates a voluntary listing scheme (MDRS). Devices are not formally registered; therefore no formal reliance pathway applies.                                                                                                              | NOT          |