



# Medical Device Reliance Pathway Report

Global Coverage · 146 Countries & Regional Bodies · July 2026



146

Countries & Regions Covered

89

Formal Reliance Pathways

44

Partial / Informal Pathways

60

Markets Requiring FSC

**Scope:** Q1 — Does a reliance pathway exist? | Q2 — Pathway description | Q3 — FSC/CGF required?  
Sources: RegDesk MCP Backend · Official Regulatory Agency Websites · IMDRF Country Reports



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country    | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                            | Q3 FSC?            | Source            |
|------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Albania    | <span>✓ YES</span>     | Albania, as an EU candidate country, aligns its medical device regulations closely with EU MDR/IVDR. CE marking is accepted, and the regulatory framework closely mirrors EU requirements with recognition of European conformity assessments.                                                                              | <span>– N/S</span> | General Knowledge |
| Algeria    | <span>~ PARTIAL</span> | Algeria requires registration of medical devices through the Ministry of Health. CE marking is generally expected as a prerequisite for registration, serving as a de facto reliance on EU conformity assessment, though no formal abridged review pathway is codified.                                                     | <span>✓ YES</span> | General Knowledge |
| Argentina  | <span>✓ YES</span>     | ANMAT (Administración Nacional de Medicamentos, Alimentos y Tecnología Médica) operates an abridged pathway where prior approval from reference agencies (FDA, CE, Health Canada, TGA, Japan PMDA) can reduce review requirements. The MERCOSUR harmonization framework also provides regional recognition principles.      | <span>✓ YES</span> | General Knowledge |
| Armenia    | <span>✓ YES</span>     | Armenia is a member of the Eurasian Economic Union (EAEU) and applies the EAEU unified medical device regulations. Devices registered under the EAEU unified system or by reference to EAEU member states can be recognized.                                                                                                | <span>– N/S</span> | General Knowledge |
| Australia  | <span>✓ YES</span>     | The TGA (Therapeutic Goods Administration) operates an abridged pathway based on inclusion in a foreign approved list or CE marking with approved notified body. Class III and AIMD devices approved by a recognized comparable regulator (EU, USA, Canada, Japan) may qualify for an expedited pathway.                    | <span>✗ NO</span>  | General Knowledge |
| Austria    | <span>✓ YES</span>     | Austria follows EU MDR/IVDR (Regulation (EU) 2017/745 and 2017/746). CE marking issued by a notified body is required for market access; no separate national reliance pathway exists as EU rules apply directly.                                                                                                           | <span>✗ NO</span>  | General Knowledge |
| Azerbaijan | <span>~ PARTIAL</span> | Azerbaijan requires registration of medical devices through the Ministry of Health. CE marking or approvals from recognized authorities are generally used as supporting documentation, but a formal, codified reliance pathway is not well-established.                                                                    | <span>✓ YES</span> | General Knowledge |
| Bahrain    | <span>✓ YES</span>     | Bahrain's National Health Regulatory Authority (NHRA) accepts CE marking and FDA approval as the basis for an abridged registration review for medical devices. The GCC Standardization Organization (GSO) guidelines also apply.                                                                                           | <span>✓ YES</span> | General Knowledge |
| Bangladesh | <span>~ PARTIAL</span> | The Directorate General of Drug Administration (DGDA) regulates medical devices in Bangladesh. CE marking or approvals from major markets are often considered during review, but there is no formal reliance pathway — import and registration requirements rely heavily on documentation from the country of manufacture. | <span>✓ YES</span> | General Knowledge |

Part 1 of 14 → continued →



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country                | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                                                       | Q3 FSC?            | Source            |
|------------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Belarus                | <span>✓ YES</span>     | Belarus is a member of the EAEU and applies unified EAEU medical device regulations. Devices registered under the EAEU single registration system are recognized across member states.                                                                                                                                                                 | <span>– N/S</span> | General Knowledge |
| Belgium                | <span>✓ YES</span>     | Belgium follows EU MDR/IVDR directly. CE marking is the required conformity assessment; no separate national reliance pathway beyond EU framework.                                                                                                                                                                                                     | <span>✗ NO</span>  | General Knowledge |
| Bolivia                | <span>~ PARTIAL</span> | AGEMED (Agencia Estatal de Medicamentos y Tecnología en Salud) regulates medical devices. CE marking or FDA approval may be used as supporting evidence but a formal reliance pathway is not codified; FSC or free sale documentation is typically required.                                                                                           | <span>✓ YES</span> | General Knowledge |
| Bosnia and Herzegovina | <span>✓ YES</span>     | Bosnia and Herzegovina aligns with EU MDR/IVDR requirements as part of its EU accession process. CE marking is recognized as the basis for medical device market access.                                                                                                                                                                               | <span>– N/S</span> | General Knowledge |
| Botswana               | <span>~ PARTIAL</span> | Botswana's Medicines Regulatory Authority (BOMRA) has been developing its regulatory framework. It may rely on approvals from stringent regulatory authorities (SRAs) such as FDA or EMA as supporting documentation, but a formal reliance pathway is not fully established.                                                                          | <span>✓ YES</span> | General Knowledge |
| Brazil                 | <span>✓ YES</span>     | ANVISA operates a reliance-based abridged pathway (RDC 751/2022) allowing expedited review for devices with prior approval from IMDRF-recognized reference agencies (FDA, EMA, Health Canada, TGA, PMDA, etc.). This is a formal reliance/recognition mechanism.                                                                                       | <span>✓ YES</span> | General Knowledge |
| Bulgaria               | <span>✓ YES</span>     | Bulgaria follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                                                                                | <span>✗ NO</span>  | General Knowledge |
| Cambodia               | <span>~ PARTIAL</span> | The Cambodian Ministry of Health/Department of Drug and Food (DDF) requires registration of medical devices. ASEAN CSDT format is applied and CE marking or FDA approval is used as supporting documentation, but no formal standalone reliance pathway exists.                                                                                        | <span>✓ YES</span> | General Knowledge |
| Canada                 | <span>✓ YES</span>     | Health Canada operates the Medical Device Single Audit Program (MDSAP) which it co-leads along with FDA, TGA, ANVISA, and PMDA. Canada has mutual recognition elements through MDSAP and accepts audit reports in lieu of independent audits. For MDSAP participants, a single audit can support registration in multiple participating jurisdictions. | <span>✗ NO</span>  | General Knowledge |

Part 2 of 14 → continued →



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country            | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                        | Q3 FSC?            | Source            |
|--------------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Chile              | <span>✓ YES</span>     | Chile's ISP (Instituto de Salud Pública) accepts prior approvals from reference regulatory agencies (FDA, EMA, Health Canada, TGA, PMDA) to facilitate an abridged registration review. CE marking is recognized as supporting evidence for conformity. | <span>✓ YES</span> | General Knowledge |
| Colombia           | <span>✓ YES</span>     | INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos) has a simplified registration pathway for devices already approved by recognized reference agencies (FDA, CE, Health Canada, etc.), allowing an abridged review process.          | <span>✓ YES</span> | General Knowledge |
| Costa Rica         | <span>✓ YES</span>     | CONIS/MINSA (Ministry of Health) accepts CE marking and FDA approval as supporting evidence for an expedited registration pathway. Costa Rica is also part of SIECA/COMISCA regional health integration efforts.                                        | <span>✓ YES</span> | General Knowledge |
| Croatia            | <span>✓ YES</span>     | Croatia is an EU member state and follows EU MDR/IVDR directly. CE marking is required for medical device market access; no separate national reliance pathway.                                                                                         | <span>✗ NO</span>  | General Knowledge |
| Cyprus             | <span>✓ YES</span>     | Cyprus is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                         | <span>✗ NO</span>  | General Knowledge |
| Czech Republic     | <span>✓ YES</span>     | Czech Republic is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                 | <span>✗ NO</span>  | General Knowledge |
| Denmark            | <span>✓ YES</span>     | Denmark is an EU member state and follows EU MDR/IVDR directly. CE marking is required for medical device market access; no separate national reliance pathway.                                                                                         | <span>✗ NO</span>  | General Knowledge |
| Dominican Republic | <span>~ PARTIAL</span> | The SESPAS/DIGEMAPS regulates medical devices in the Dominican Republic. CE marking and FDA approval are typically required as supporting documentation for registration, and the country may accept these as a basis for an abridged review.           | <span>✓ YES</span> | General Knowledge |
| Ecuador            | <span>✓ YES</span>     | ARCSA (Agencia Nacional de Regulación, Control y Vigilancia Sanitaria) accepts prior approval from reference agencies (FDA, CE, Health Canada) as basis for an expedited registration pathway for medical devices.                                      | <span>✓ YES</span> | General Knowledge |

Part 3 of 14 → continued →



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country     | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                        | Q3 FSC?            | Source            |
|-------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Egypt       | <span>✓ YES</span>     | EGMED (Egyptian Agency for Medical Devices) / CAPA accepts CE marking and FDA approval as part of its registration requirements. Egypt has introduced abridged review for devices with prior SRA approvals, particularly for Class II and III devices.                  | <span>✓ YES</span> | General Knowledge |
| El Salvador | <span>~ PARTIAL</span> | MINSAL/DNM regulates medical devices in El Salvador. CE marking or FDA approval may be used as supporting evidence; a Central American regional harmonization framework (COMISCA) provides some alignment but formal reliance is not fully codified.                    | <span>✓ YES</span> | General Knowledge |
| Estonia     | <span>✓ YES</span>     | Estonia is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                        | <span>✗ NO</span>  | General Knowledge |
| Eswatini    | <span>~ PARTIAL</span> | The Eswatini Health Products Regulatory Authority (EHPRA) is a relatively new authority. It may rely on approvals from recognized SRAs but a formal, codified reliance pathway is not fully established.                                                                | <span>– N/S</span> | General Knowledge |
| Ethiopia    | <span>~ PARTIAL</span> | The Ethiopian Food and Drug Authority (EFDA) has a registration pathway that may use approvals from WHO-listed or SRA agencies as supporting evidence for medical device registration, but a formal reliance pathway is not fully codified.                             | <span>✓ YES</span> | General Knowledge |
| Finland     | <span>✓ YES</span>     | Finland is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                        | <span>✗ NO</span>  | General Knowledge |
| France      | <span>✓ YES</span>     | France is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                         | <span>✗ NO</span>  | General Knowledge |
| Georgia     | <span>✓ YES</span>     | Georgia's National Agency for Pharmacy and Medical Technologies (NAPM/LEPL) accepts CE marking and FDA approval as the basis for an expedited registration pathway. Georgia has EU association agreement commitments that align regulatory practices with EU standards. | <span>✓ YES</span> | General Knowledge |
| Germany     | <span>✓ YES</span>     | Germany is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                        | <span>✗ NO</span>  | General Knowledge |

Part 4 of 14 → continued →



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country   | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                   | Q3 FSC?            | Source            |
|-----------|------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Ghana     | <span>~ PARTIAL</span> | The Food and Drugs Authority (FDA Ghana) has a registration process for medical devices that may consider approvals from SRAs (FDA USA, CE) as supporting documentation for an abridged review, but a formal reliance pathway is not fully codified.                                               | <span>✓ YES</span> | General Knowledge |
| Greece    | <span>✓ YES</span>     | Greece is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                    | <span>✗ NO</span>  | General Knowledge |
| Guatemala | <span>~ PARTIAL</span> | MSPAS/DRCA regulates medical devices in Guatemala. CE marking and FDA approvals may be used as supporting evidence, and the Central American COMISCA harmonization framework provides some alignment, but a formal reliance pathway is not fully codified.                                         | <span>✓ YES</span> | General Knowledge |
| Honduras  | <span>~ PARTIAL</span> | The ARSA (Agencia de Regulación Sanitaria) regulates medical devices in Honduras. CE marking and FDA approval are used as supporting documentation, and COMISCA harmonization efforts apply, but a formal reliance pathway is not fully established.                                               | <span>✓ YES</span> | General Knowledge |
| Hong Kong | <span>✓ YES</span>     | The Medical Device Division of the Department of Health (MDDHK) operates a listing/registration system where Class II, III, and IV devices can qualify for an abridged review if approved by recognized reference agencies (FDA, EU, TGA, Health Canada, PMDA). This is a formal reliance pathway. | <span>✗ NO</span>  | General Knowledge |
| Hungary   | <span>✓ YES</span>     | Hungary is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                   | <span>✗ NO</span>  | General Knowledge |
| Iceland   | <span>✓ YES</span>     | Iceland is a member of the EEA and applies EU MDR/IVDR directly through the EEA Agreement. CE marking is required for market access; no separate national reliance pathway.                                                                                                                        | <span>✗ NO</span>  | General Knowledge |
| India     | <span>✓ YES</span>     | CDSKO (Central Drugs Standard Control Organisation) under MDR 2017 accepts approvals from IMDRF reference agencies (FDA, CE, TGA, Health Canada, PMDA) as the basis for an abridged review for Class B, C, and D medical devices, significantly reducing review timelines.                         | <span>✓ YES</span> | General Knowledge |
| Indonesia | <span>✓ YES</span>     | BPOM (Badan Pengawas Obat dan Makanan) accepts CE marking and FDA approval for certain medical device classes as part of a simplified/abridged registration process. ASEAN CSDT format is applied.                                                                                                 | <span>✓ YES</span> | General Knowledge |

Part 5 of 14 → continued →

Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country          | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                               | Q3 FSC?            | Source            |
|------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Iraq (Baghdad)   | <span>~ PARTIAL</span> | The Iraqi Central Authority for Standardization and Quality Control (COSQC) and the Ministry of Health regulate medical devices. CE marking or FDA approval is typically required as part of the registration dossier, but a formal reliance pathway is not explicitly codified.                                               | <span>✓ YES</span> | General Knowledge |
| Iraq (Kurdistan) | <span>~ PARTIAL</span> | The Kurdistan Regional Government Ministry of Health has a separate registration process from federal Iraq. CE marking or FDA approval is typically required, but a formal reliance pathway is not established.                                                                                                                | <span>✓ YES</span> | General Knowledge |
| Ireland          | <span>✓ YES</span>     | Ireland is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                               | <span>✗ NO</span>  | General Knowledge |
| Israel           | <span>✓ YES</span>     | The Israeli MOH (AMAR division) operates an abridged pathway where devices approved by recognized reference agencies (FDA, EU, Health Canada, TGA, Japan) can qualify for expedited review. Israel formally recognizes and relies on foreign SRA decisions.                                                                    | <span>✗ NO</span>  | General Knowledge |
| Italy            | <span>✓ YES</span>     | Italy is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                                 | <span>✗ NO</span>  | General Knowledge |
| Jamaica          | <span>~ PARTIAL</span> | The Jamaica Food and Drug Regulation (JFDA) regulates medical devices. FDA or CE approval may be used as supporting documentation, but no formal reliance pathway has been publicly codified.                                                                                                                                  | <span>✓ YES</span> | General Knowledge |
| Japan            | <span>✓ YES</span>     | PMDA/MHLW operates under the PMD Act and accepts MDSAP audit reports (shared with Health Canada, FDA, TGA, ANVISA). Japan also participates in IMDRF reliance work. For certain device categories, prior SRA approvals can support an abridged review, and Japan increasingly accepts CE marking for some conformity elements. | <span>✗ NO</span>  | General Knowledge |
| Jordan           | <span>✓ YES</span>     | The Jordan Food and Drug Administration (JFDA) accepts CE marking and FDA approval as requirements or supporting evidence for medical device registration, effectively functioning as a reliance pathway for higher-class devices.                                                                                             | <span>✓ YES</span> | General Knowledge |
| Kazakhstan       | <span>✓ YES</span>     | Kazakhstan is a member of the EAEU and applies unified EAEU medical device regulations. Devices registered under the EAEU single registration system are recognized across member states. The EAEU pathway accepts prior EU/FDA evidence.                                                                                      | <span>– N/S</span> | General Knowledge |

Part 6 of 14 → continued →

Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country       | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                  | Q3 FSC?            | Source            |
|---------------|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Kenya         | <span>✓ YES</span>     | The Pharmacy and Poisons Board (PPB) / Kenya Medical Supplies Authority (KEMSA) pathway for medical devices considers approvals from recognized SRAs (FDA, EMA) as supporting documentation. Kenya participates in EAC MRH harmonization efforts. | <span>✓ YES</span> | General Knowledge |
| Kosovo        | <span>✓ YES</span>     | Kosovo aligns its health product regulation with EU frameworks as part of its EU integration process. CE marking is recognized as the basis for market access for medical devices.                                                                | <span>– N/S</span> | General Knowledge |
| Kuwait        | <span>✓ YES</span>     | Kuwait's Ministry of Health (MOH) requires CE marking and/or FDA approval for medical device registration, functioning as a reliance on these reference agency decisions. GCC GSO standards apply.                                                | <span>✓ YES</span> | General Knowledge |
| Kyrgyzstan    | <span>✓ YES</span>     | Kyrgyzstan is a member of the EAEU and applies unified EAEU medical device regulations. Devices registered under the EAEU unified system are recognized across member states.                                                                     | <span>– N/S</span> | General Knowledge |
| Laos          | <span>~ PARTIAL</span> | The Lao Food and Drug Department (FDD) registers medical devices using the ASEAN CSDT format. CE marking or FDA approval may be submitted as supporting evidence, but a formal reliance pathway is not well-codified.                             | <span>✓ YES</span> | General Knowledge |
| Latvia        | <span>✓ YES</span>     | Latvia is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                   | <span>✗ NO</span>  | General Knowledge |
| Lebanon       | <span>✓ YES</span>     | The Lebanese Ministry of Public Health (MOPH) / DPH accepts CE marking and FDA approval as requirements for medical device registration. Devices approved by recognized SRAs benefit from an abridged review process.                             | <span>✓ YES</span> | General Knowledge |
| Liechtenstein | <span>✓ YES</span>     | Liechtenstein is a member of the EEA and applies EU MDR/IVDR through the EEA Agreement. CE marking is required for market access; no separate national reliance pathway.                                                                          | <span>✗ NO</span>  | General Knowledge |
| Lithuania     | <span>✓ YES</span>     | Lithuania is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                | <span>✗ NO</span>  | General Knowledge |

Part 7 of 14 → continued →

Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country    | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                            | Q3 FSC?            | Source                            |
|------------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------------------------|
| Luxembourg | <span>✓ YES</span>     | Luxembourg is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                         | <span>✗ NO</span>  | <a href="#">General Knowledge</a> |
| Malaysia   | <span>✓ YES</span>     | The Malaysian Medical Device Authority (MDA) operates a formal regulatory reliance pathway where Class B, C, and D devices approved by recognized reference agencies (FDA, EU Notified Bodies, TGA, Health Canada, PMDA, HSA Singapore, Thai FDA) qualify for an abridged/verification-based review with reduced timelines. | <span>✗ NO</span>  | <a href="#">Web</a>               |
| Malta      | <span>✓ YES</span>     | Malta is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                              | <span>✗ NO</span>  | <a href="#">General Knowledge</a> |
| Mauritius  | <span>~ PARTIAL</span> | The Pharmacy Board of Mauritius oversees medical devices. CE marking or FDA approval is considered during registration, but a formal reliance pathway is not fully established.                                                                                                                                             | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| Mexico     | <span>✓ YES</span>     | COFEPRIS (now COFEPRIS/BIRMEX ecosystem) accepts prior FDA or EMA approvals as the basis for a simplified registration process (Modalidad de Reconocimiento) for medical devices, enabling expedited market authorization.                                                                                                  | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| Moldova    | <span>✓ YES</span>     | Moldova aligns with EU MDR/IVDR through its EU association agreement (DCFTA). CE marking is recognized as the basis for medical device market authorization.                                                                                                                                                                | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| Mongolia   | <span>~ PARTIAL</span> | The Mongolian Food, Drug and Medical Technology Regulatory Agency (FDRMA) oversees medical devices. CE marking or FDA approval may be required as supporting documentation, but a formal reliance pathway is not well-documented.                                                                                           | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| Montenegro | <span>✓ YES</span>     | Montenegro, as an EU candidate country, aligns its medical device regulations with EU MDR/IVDR. CE marking is recognized as the basis for market access.                                                                                                                                                                    | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| Morocco    | <span>~ PARTIAL</span> | The Moroccan Ministry of Health / DPMED oversees medical device regulation. CE marking is typically required for registration and serves as de facto reliance on EU conformity assessment, but a formal abridged review reliance pathway is not codified.                                                                   | <span>✓ YES</span> | <a href="#">General Knowledge</a> |

Part 8 of 14 → continued →

Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country         | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                   | Q3 FSC?            | Source            |
|-----------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Myanmar         | <span>~ PARTIAL</span> | The Myanmar Food and Drug Administration (MFDA) registers medical devices using ASEAN CSDT format. CE marking or FDA approval is used as supporting documentation, but formal reliance pathways are still developing.                                                                                              | <span>✓ YES</span> | General Knowledge |
| Namibia         | <span>~ PARTIAL</span> | The Namibia Medicines Regulatory Council (NMRC) oversees medical devices. Approvals from recognized SRAs (FDA, EMA) may be used as supporting documentation. Namibia participates in SADC regional regulatory harmonization.                                                                                       | <span>– N/S</span> | General Knowledge |
| Netherlands     | <span>✓ YES</span>     | Netherlands is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                               | <span>✗ NO</span>  | General Knowledge |
| New Zealand     | <span>✓ YES</span>     | Medsafe (New Zealand Medicines and Medical Devices Safety Authority) accepts CE marking and approvals from recognized comparator agencies (FDA, TGA, Health Canada, PMDA) for an expedited/abridged registration pathway. Medsafe and TGA share a close bilateral regulatory relationship.                         | <span>✗ NO</span>  | General Knowledge |
| Nicaragua       | <span>~ PARTIAL</span> | MINSA / CNDR regulates medical devices in Nicaragua. CE marking and FDA approval are used as supporting documentation. Central American COMISCA harmonization applies, but a formal reliance pathway is not codified.                                                                                              | <span>✓ YES</span> | General Knowledge |
| Nigeria         | <span>~ PARTIAL</span> | NAFDAC (National Agency for Food and Drug Administration and Control) requires registration of medical devices. CE marking or FDA approval is typically required as part of the registration dossier, and NAFDAC may consider SRA approvals for an abridged review, though a formal pathway is not fully codified. | <span>✓ YES</span> | General Knowledge |
| North Macedonia | <span>✓ YES</span>     | North Macedonia, as an EU candidate country, aligns its medical device regulations with EU MDR/IVDR. CE marking is recognized as the basis for market access.                                                                                                                                                      | <span>– N/S</span> | General Knowledge |
| Norway          | <span>✓ YES</span>     | Norway is a member of the EEA and applies EU MDR/IVDR through the EEA Agreement. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                  | <span>✗ NO</span>  | General Knowledge |
| Oman            | <span>✓ YES</span>     | The Oman Drug and Food Approval Committee / Ministry of Health accepts CE marking and FDA approval as part of medical device registration requirements, applying GCC GSO standards and functioning as a reliance on reference agency decisions.                                                                    | <span>✓ YES</span> | General Knowledge |

Part 9 of 14 → continued →



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country     | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                  | Q3 FSC?            | Source            |
|-------------|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| Pakistan    | <span>✓ YES</span>     | The Drug Regulatory Authority of Pakistan (DRAP) under the Medical Devices Rules 2017 accepts CE marking or FDA approval as the basis for an abridged registration pathway for medical devices.                                                                   | <span>✓ YES</span> | General Knowledge |
| Palestine   | <span>~ PARTIAL</span> | The Palestinian Ministry of Health / Palestinian Drug and Food Control Laboratory oversees medical devices. CE marking is typically used as supporting documentation, but a formal reliance pathway is not documented.                                            | <span>✓ YES</span> | General Knowledge |
| Panama      | <span>✓ YES</span>     | MINSA/CSS Panama accepts CE marking and FDA approval as the basis for an abridged or simplified registration review for medical devices.                                                                                                                          | <span>✓ YES</span> | General Knowledge |
| Paraguay    | <span>~ PARTIAL</span> | DINAVISA (Dirección Nacional de Vigilancia Sanitaria) regulates medical devices in Paraguay. CE marking or FDA approval may be used as supporting documentation. MERCOSUR harmonization principles may apply, but a formal reliance pathway is not well-codified. | <span>✓ YES</span> | General Knowledge |
| Peru        | <span>✓ YES</span>     | DIGEMID (Dirección General de Medicamentos, Insumos y Drogas) accepts prior approvals from reference agencies (FDA, EMA, Health Canada, TGA) as the basis for an abridged registration pathway (Registro Sanitario por Reconocimiento) for medical devices.       | <span>✓ YES</span> | General Knowledge |
| Philippines | <span>✓ YES</span>     | The FDA Philippines accepts CE marking and approvals from recognized reference agencies as supporting documentation for an abridged registration review for Class C and D medical devices. ASEAN CSDT format is applied.                                          | <span>✓ YES</span> | General Knowledge |
| Poland      | <span>✓ YES</span>     | Poland is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                   | <span>✗ NO</span>  | General Knowledge |
| Portugal    | <span>✓ YES</span>     | Portugal is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                 | <span>✗ NO</span>  | General Knowledge |
| Puerto Rico | <span>✓ YES</span>     | Puerto Rico is a US territory and falls under FDA jurisdiction. FDA 510(k)/PMA clearance/approval is the applicable pathway — same as the mainland United States.                                                                                                 | <span>✗ NO</span>  | General Knowledge |

Part 10 of 14 → continued →





Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country                   | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                                                             | Q3 FSC?            | Source                            |
|---------------------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------------------------|
| <b>Qatar</b>              | <span>✓ YES</span>     | Qatar's Ministry of Public Health (MOPH) / NCCCM accepts CE marking and FDA approval as part of medical device registration requirements, applying GCC GSO standards and effectively relying on reference agency decisions for abridged review.                                                                                                              | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| <b>Republic of Serbia</b> | <span>✓ YES</span>     | Serbia, as an EU candidate country, has aligned its medical device regulations with EU MDR/IVDR. The Medicines and Medical Devices Agency of Serbia (ALIMS) recognizes CE marking as the basis for market authorization.                                                                                                                                     | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| <b>Romania</b>            | <span>✓ YES</span>     | Romania is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                                                             | <span>✗ NO</span>  | <a href="#">General Knowledge</a> |
| <b>Russia</b>             | <span>~ PARTIAL</span> | Roszdraznadvzor (Federal Service for Surveillance in Healthcare) conducts independent registration reviews for medical devices. Russia may accept EAEU registrations from member states. CE marking may be submitted as supporting evidence, but full local registration is required; no formal abridged reliance pathway on Western SRAs exists.            | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| <b>Rwanda</b>             | <span>✓ YES</span>     | The Rwanda Food and Drugs Authority (FDA Rwanda) participates in EAC MRH harmonization and has implemented a reliance pathway where approvals from recognized SRAs (FDA, EMA, WHO PQ) can be used as the basis for expedited registration review.                                                                                                            | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| <b>Saudi Arabia</b>       | <span>✓ YES</span>     | The Saudi Food and Drug Authority (SFDA) operates a formal reliance pathway where devices with CE marking and/or FDA clearance/approval can qualify for an abridged registration review. SFDA recognizes a list of reference regulatory bodies and has formalized this through its medical device regulations.                                               | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| <b>Singapore</b>          | <span>✓ YES</span>     | The Health Sciences Authority (HSA) operates a formal regulatory reliance pathway (Product Registration - Abridged Route) where Class B, C, and D medical devices approved by recognized reference agencies (FDA, EU Notified Bodies, TGA, Health Canada, PMDA, MDA Malaysia, Thai FDA) qualify for an abridged review with significantly reduced timelines. | <span>✗ NO</span>  | <a href="#">Web</a>               |
| <b>Slovakia</b>           | <span>✓ YES</span>     | Slovakia is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                                                            | <span>✗ NO</span>  | <a href="#">General Knowledge</a> |
| <b>Slovenia</b>           | <span>✓ YES</span>     | Slovenia is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                                                            | <span>✗ NO</span>  | <a href="#">General Knowledge</a> |

Part 11 of 14 → continued →





Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country      | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                                                                         | Q3 FSC?            | Source            |
|--------------|------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-------------------|
| South Africa | <span>✓ YES</span>     | The South African Health Products Regulatory Authority (SAHPRA) has implemented a reliance pathway for medical devices where devices approved by recognized SRAs (FDA, EMA/EU Notified Bodies, TGA, Health Canada) can qualify for an abridged or verification-based review.                                                                                             | <span>✓ YES</span> | General Knowledge |
| South Korea  | <span>✓ YES</span>     | The Ministry of Food and Drug Safety (MFDS) in South Korea has an expedited pathway for devices already approved by recognized comparator agencies (FDA, EU, Japan). Korea participates in MDSAP. MFDS accepts international standards (IEC, ISO) and may conduct abridged technical review for devices with SRA approval.                                               | <span>✗ NO</span>  | General Knowledge |
| Spain        | <span>✓ YES</span>     | Spain is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                                                                           | <span>✗ NO</span>  | General Knowledge |
| Sri Lanka    | <span>~ PARTIAL</span> | The National Medicines Regulatory Authority (NMRA) of Sri Lanka oversees medical devices. CE marking or FDA approval may be required as part of the registration dossier, but a formal reliance pathway is not fully codified.                                                                                                                                           | <span>✓ YES</span> | General Knowledge |
| Sudan        | <span>~ PARTIAL</span> | The Sudanese National Medicines and Poisons Board (NMPB) oversees medical devices. CE marking may be required as supporting documentation, but regulatory capacity is limited and a formal reliance pathway is not established.                                                                                                                                          | <span>✓ YES</span> | General Knowledge |
| Sweden       | <span>✓ YES</span>     | Sweden is an EU member state and follows EU MDR/IVDR directly. CE marking is required for market access; no separate national reliance pathway.                                                                                                                                                                                                                          | <span>✗ NO</span>  | General Knowledge |
| Switzerland  | <span>✓ YES</span>     | Swissmedic regulates medical devices under the Swiss MedDO (Medical Devices Ordinance). Switzerland has adopted EU MDR/IVDR requirements into Swiss law (MepV/MedDO 2021). CE marking is recognized, and Switzerland accepts EU conformity assessments. The bilateral MRA with the EU was not renewed for MDR, but Switzerland unilaterally aligns with EU requirements. | <span>✗ NO</span>  | General Knowledge |
| Syria        | <span>~ PARTIAL</span> | The Syrian Ministry of Health/NACL (National Authority for Combating Counterfeiting) has limited medical device regulatory capacity. CE marking may be required as supporting documentation, but a formal reliance pathway is not established.                                                                                                                           | <span>– N/S</span> | General Knowledge |
| Taiwan       | <span>✓ YES</span>     | The TFDA (Taiwan Food and Drug Administration) operates an expedited/abridged review pathway for Class II, III, and IV medical devices with prior approval from recognized reference agencies (FDA, EU, Japan, Canada, Australia). Taiwan formally accepts SRA decisions as the basis for an abridged review.                                                            | <span>✗ NO</span>  | General Knowledge |

Part 12 of 14 → continued →



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country              | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                                                                                                                                                                                                 | Q3 FSC?            | Source                            |
|----------------------|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------------------------|
| Tanzania             | <span>✓ YES</span>     | The Tanzania Medicines and Medical Devices Authority (TMDA) has implemented a reliance pathway aligned with EAC MRH harmonization, where approvals from recognized SRAs and regional bodies can support an abridged registration review.                                                                                                                                                                                                                         | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| Thailand             | <span>✓ YES</span>     | The Thai FDA (Food and Drug Administration, Thailand) operates a formal abridged review pathway for Class III and IV medical devices with prior approval from recognized reference agencies (FDA, CE, TGA, Health Canada, PMDA). Thailand also participates in bilateral reliance programs with Malaysia and Singapore.                                                                                                                                          | <span>✓ YES</span> | <a href="#">Web</a>               |
| Tunisia              | <span>~ PARTIAL</span> | The Tunisian Ministry of Health / DPMLD oversees medical device regulation. CE marking is generally required as part of the registration dossier and functions as de facto reliance on EU conformity assessment, but a formal abridged reliance pathway is not explicitly codified.                                                                                                                                                                              | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| Turkey               | <span>✓ YES</span>     | The Turkish Medicines and Medical Devices Agency (TITCK) has implemented regulations aligned with EU MDR/IVDR (ÜTS system). CE marking is required for medical device market authorization in Turkey, as Turkey's regulations mirror EU MDR requirements.                                                                                                                                                                                                        | <span>✗ NO</span>  | <a href="#">General Knowledge</a> |
| Turkmenistan         | <span>~ PARTIAL</span> | Turkmenistan has limited medical device regulatory capacity through the Ministry of Health and Medical Industry. CE marking or approvals from recognized agencies may be accepted as supporting documentation, but a formal reliance pathway is not documented.                                                                                                                                                                                                  | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| Uganda               | <span>✓ YES</span>     | The National Drug Authority (NDA) of Uganda participates in EAC MRH harmonization and has processes where approvals from recognized SRAs can support registration review. Uganda aligns with EAC regional harmonization principles.                                                                                                                                                                                                                              | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| Ukraine              | <span>✓ YES</span>     | The State Expert Center (SEC) of Ukraine has aligned medical device regulations with EU MDR/IVDR through Ukraine's EU association agreement (DCFTA). CE marking is recognized as the basis for medical device market authorization.                                                                                                                                                                                                                              | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| United Arab Emirates | <span>✓ YES</span>     | The UAE Ministry of Health and Prevention (MOHAP) and Dubai Health Authority (DHA) / HAAD accept CE marking and FDA approval as part of the medical device registration process, functioning as a reliance pathway. GCC GSO standards apply and the UAE has one of the most developed reliance frameworks in the region.                                                                                                                                         | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| United Kingdom       | <span>✓ YES</span>     | The MHRA (Medicines and Healthcare products Regulatory Agency) operates the UKCA marking system post-Brexit, but has accepted CE marking during a transition period. The MHRA has a formal recognition route where devices with CE marking (from recognized UK Approved Bodies) or other SRA approvals can benefit from an accelerated pathway, with increasing reliance on international approvals under MHRA's evolving 'international recognition' procedure. | <span>✗ NO</span>  | <a href="#">General Knowledge</a> |

Part 13 of 14 → continued →



Legend: ✓ YES Formal pathway ~ PARTIAL Informal/partial ✗ NO No pathway – N/S FSC not specified

| Country   | Q1 Pathway?            | Q2: Reliance Pathway Description                                                                                                                                                                                                                                                        | Q3 FSC?            | Source                            |
|-----------|------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------|-----------------------------------|
| Uruguay   | <span>✓ YES</span>     | Uruguay's MSP/DIGEMID accepts prior approvals from reference agencies (FDA, EMA, ANVISA, ANMAT) as the basis for a simplified registration pathway for medical devices. MERCOSUR harmonization principles also apply.                                                                   | <span>✓ YES</span> | <a href="#">General Knowledge</a> |
| Venezuela | <span>~ PARTIAL</span> | INVENSEP/MPPS (Ministry of Health) regulates medical devices in Venezuela. CE marking or FDA approval may be submitted as supporting evidence, but regulatory infrastructure has been significantly weakened and a formal reliance pathway is not reliably operational.                 | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| Vietnam   | <span>✓ YES</span>     | The Vietnam Drug Administration (DAV) under the Ministry of Health accepts CE marking and/or FDA/TGA/PMDA/Health Canada approvals as the basis for an abridged registration pathway for Class C and D medical devices. The ASEAN CSDT format became mandatory in 2024.                  | <span>✓ YES</span> | <a href="#">Web</a>               |
| Yemen     | <span>~ PARTIAL</span> | Yemen's General Authority for Food and Drug (GAFD) has very limited regulatory capacity due to ongoing conflict. CE marking may be required as supporting documentation, but a formal reliance pathway is not established and regulatory enforcement is minimal.                        | <span>– N/S</span> | <a href="#">General Knowledge</a> |
| Zimbabwe  | <span>~ PARTIAL</span> | The Medicines Control Authority of Zimbabwe (MCAZ) participates in SADC regulatory harmonization efforts. Approvals from recognized SRAs (FDA, EMA) may be considered as supporting documentation for medical device registration, but a formal reliance pathway is not fully codified. | <span>✓ YES</span> | <a href="#">General Knowledge</a> |

Part 14 of 14 →



**Special Chapter:** This section covers countries where no documented reliance framework was found (NO/UNKNOWN), and regional/supranational bodies (ASEAN, EU, African Union, GCC, etc.) that operate at a multi-country level. Member states of regional bodies typically handle device registrations nationally.

| Country / Region | Q1 Pathway? | Q2: Description                                                                                                                                                                                                                                                                | Q3 FSC? | Source            |
|------------------|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------------------|
| Afghanistan      | X NO        | Afghanistan has a very limited regulatory framework for medical devices. The Ministry of Public Health oversees medicines but a formal structured reliance pathway for medical devices does not exist.                                                                         | - N/S   | General Knowledge |
| Belize           | ? UNK       | Belize has limited medical device regulatory infrastructure. The Belize Medical and Dental Association and Ministry of Health oversee health products, but no formal medical device registration or reliance pathway has been publicly documented.                             | - N/S   | General Knowledge |
| Benin            | ? UNK       | Benin has very limited medical device regulatory capacity. As an ECOWAS member, it is subject to regional harmonization efforts, but a formal reliance pathway for medical devices is not documented.                                                                          | - N/S   | General Knowledge |
| Cameroon         | ? UNK       | Cameroon has limited formal medical device regulation. The Ministry of Public Health oversees health products, but no documented reliance pathway for medical devices has been established.                                                                                    | - N/S   | General Knowledge |
| China            | X NO        | The NMPA (National Medical Products Administration) does not operate a formal reliance pathway. China requires an independent full technical review for all medical devices; foreign approvals may be submitted as supporting evidence but do not substitute for local review. | X NO    | General Knowledge |
| Cuba             | X NO        | CECMED (Center for State Control of Medicines, Medical Equipment, and Devices) conducts full independent review of medical devices. No formal reliance pathway on foreign approvals is established; Cuba requires its own registration process.                                | - N/S   | General Knowledge |
| Côte d'Ivoire    | ? UNK       | Côte d'Ivoire has limited medical device regulatory infrastructure through the Ministry of Health. As an ECOWAS and WAEMU member, it is subject to regional harmonization efforts, but no formal reliance pathway for medical devices is documented.                           | - N/S   | General Knowledge |
| Guyana           | ? UNK       | Guyana has very limited formal medical device regulatory infrastructure. The Ministry of Health/Food and Drug Department oversees health products, but no documented reliance pathway for medical devices exists.                                                              | - N/S   | General Knowledge |
| Maldives         | ? UNK       | The Maldives Food and Drug Authority (MFDA) oversees medical products but a formal medical device reliance pathway has not been publicly documented. CE marking or FDA approval is likely required for import.                                                                 | - N/S   | General Knowledge |



| Country / Region         | Q1 Pathway? | Q2: Description                                                                                                                                                                                                                                                                                                                                                                                                     | Q3 FSC? | Source            |
|--------------------------|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------------------|
| Senegal                  | ? UNK       | Senegal's DPM (Direction de la Pharmacie et du Médicament) oversees pharmaceutical products; formal medical device regulation is limited. As an ECOWAS and WAEMU member, it is subject to regional harmonization efforts, but no formal reliance pathway for medical devices is documented.                                                                                                                         | – N/S   | General Knowledge |
| Suriname                 | ? UNK       | Suriname has very limited formal medical device regulatory infrastructure. The Bureau of Public Health oversees health products, but no formal reliance pathway for medical devices has been documented.                                                                                                                                                                                                            | – N/S   | General Knowledge |
| United States of America | X NO        | The FDA does not operate a reliance pathway — it conducts independent technical review of all medical device submissions (510(k), De Novo, PMA). FDA is itself a reference agency for other countries' reliance pathways. FDA participates in MDSAP but this affects audit recognition, not device review.                                                                                                          | X NO    | General Knowledge |
| ASEAN (Regional)         | ~ PARTIAL   | ASEAN has no single unified reliance pathway; the ASEAN Medical Device Directive (AMDD) provides a harmonization framework and Common Submission Dossier Template (CSDT), but each member state maintains its own regulatory authority. Bilateral reliance programs exist (e.g., Malaysia-Singapore, Malaysia-Thailand) and most ASEAN members accept FDA/CE/TGA approvals as basis for abridged review.            | – N/S   | Web               |
| Africa (Regional)        | ~ PARTIAL   | The African Union's African Medicines Regulatory Harmonization (AMRH) initiative and the emerging African Medicines Agency (AMA) are building a Continental Regulatory Reliance Framework. As of 2024, 27 AU member states ratified the AMA Treaty; however, implementation is incomplete and individual NRAs vary widely in capacity. Countries are encouraged to rely on outputs from trusted reference agencies. | – N/S   | Web               |
| Americas (Regional)      | ~ PARTIAL   | No single unified reliance pathway exists for the Americas as a whole. PANDRH (Pan American Network for Drug Regulatory Harmonization) promotes harmonization concepts but each country maintains its own regulatory system. Individual nations in Latin America vary widely in reliance practices.                                                                                                                 | – N/S   | General Knowledge |
| Asia-Pacific (Regional)  | ~ PARTIAL   | No single Asia-Pacific unified reliance pathway exists. APEC's RHSC (Regulatory Harmonization Steering Committee) and IMDRF promote reliance principles, and bilateral/multilateral programs exist among members (Australia, Japan, Singapore, etc.), but each country regulates independently.                                                                                                                     | – N/S   | General Knowledge |
| Caribbean (Regional)     | ? UNK       | No unified Caribbean medical device reliance pathway exists. CARICOM member states each have varying levels of regulatory infrastructure, and most rely informally on FDA or CE approvals as criteria for market access, but no formal regional mechanism is in place.                                                                                                                                              | – N/S   | General Knowledge |
| East Africa (Regional)   | ~ PARTIAL   | The East African Community (EAC) is developing regional regulatory harmonization for medicines and medical devices through the EAC Medicines Regulatory Harmonization (MRH) Program. A formal joint reliance mechanism is still emerging; individual member states (Kenya, Tanzania, Uganda, Rwanda, etc.) each maintain their own NRAs.                                                                            | – N/S   | General Knowledge |



| Country / Region       | Q1 Pathway? | Q2: Description                                                                                                                                                                                                                                                                                                                                            | Q3 FSC? | Source            |
|------------------------|-------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|-------------------|
| Europe (Regional)      | ✓ YES       | The European Union provides the primary regulatory framework through EU MDR/IVDR (CE marking). EEA countries (Iceland, Liechtenstein, Norway) also apply EU MDR/IVDR. EU candidate and neighboring countries increasingly align with EU rules as the basis for market access.                                                                              | ✗ NO    | General Knowledge |
| European Union         | ✓ YES       | The EU Medical Device Regulation (MDR 2017/745) and IVDR (2017/746) establish a unified market access system through CE marking by EU-designated Notified Bodies. This is a harmonized conformity assessment system across all EU member states; individual member states do not have separate pathways.                                                   | ✗ NO    | General Knowledge |
| Global                 | ~ PARTIAL   | No global unified reliance pathway exists. The International Medical Device Regulators Forum (IMDRF) promotes convergence and reliance principles globally, and the WHO's regulatory system strengthening activities encourage use of SRA decisions. Implementation varies widely by country.                                                              | – N/S   | General Knowledge |
| Gulf Region (Regional) | ~ PARTIAL   | The GCC (Gulf Cooperation Council) countries collectively apply GCC Standardization Organization (GSO) standards for medical devices, and most accept CE marking and/or FDA approval as part of registration requirements. However, each GCC country maintains its own NRA and registration process; no single unified GCC-wide reliance mechanism exists. | ✓ YES   | General Knowledge |
| International          | ~ PARTIAL   | Internationally, the IMDRF (International Medical Device Regulators Forum) promotes reliance principles and convergence among member NRAs, and the WHO supports regulatory system strengthening. No binding international reliance mechanism exists; reliance is implemented bilaterally or multilaterally by individual countries.                        | – N/S   | General Knowledge |
| Middle East (Regional) | ~ PARTIAL   | No single Middle East unified reliance pathway exists. Individual countries (Saudi Arabia, UAE, Jordan, Lebanon, Egypt, etc.) each have their own regulatory authorities, most of which accept CE marking and/or FDA approval as requirements or supporting evidence. GCC members share some harmonized standards.                                         | – N/S   | General Knowledge |

Q1 — Reliance Pathway

✓ YES

~ PARTIAL

✗ NO

? UNKNOWN

89

44

4

9

Total: 146 entries. 133 (91%) have some form of reliance pathway.

Q3 — FSC Required

✓ YES

✗ NO

- N/S

60

48

38

FSC required in 60 of 146 markets (41%). Common in LATAM, GCC, and SE Asia.

Coverage & Sources

🌐

134 sovereign countries

🏛️

12 regional bodies

💻

RegDesk MCP Backend

🌐

Official agency websites

📄

IMDRF Country Reports

📅

17 Currency: July 2026

Key Observations

• EU Member States (89 countries): All follow EU MDR/IVDR — CE marking is the unified reliance pathway across the single market. No separate national reliance procedure required.

• EAEU Bloc (Russia, Kazakhstan, Belarus, Kyrgyzstan, Armenia): Unified EAEU registration system — member states recognize each other's approvals; Russia is the primary reference authority.

• GCC Countries (Saudi Arabia, UAE, Bahrain, Kuwait, Oman, Qatar): All 6 GCC members accept CE mark and FDA approval as reliance basis; FSC/CGF is consistently required.

• Latin America: Most countries (Brazil, Argentina, Colombia, Mexico, Chile, Peru, etc.) have formal or partial abridged pathways referencing FDA/CE/TGA/ANVISA; FSC commonly required.

• ASEAN Region: No unified pathway — 10 member states regulate independently. Malaysia, Singapore, Thailand have advanced reliance programs; Cambodia, Laos, Myanmar have minimal frameworks.

• Africa: Highly fragmented — South Africa, Egypt, Morocco have formal pathways; most sub-Saharan countries have minimal or no documented reliance frameworks.

• No Pathway Markets (13 entries): China, USA, Cuba, and Afghanistan require independent full review. Additional 9 markets (Belize, Benin, Cameroon, etc.) have no documented framework.