

Reliance Pathway Report

Global Medical Device Regulatory Analysis — 146 Markets

July 2026



This report provides a comprehensive global analysis of medical device regulatory reliance pathways, covering 134 sovereign countries and 12 regional/international frameworks. Data reflects the current regulatory landscape as researched in July 2026.

Executive Summary

A **regulatory reliance pathway** allows a national regulatory authority (NRA) to use the assessment work of a reference agency — such as the FDA (USA), European Medicines Agency / EU Notified Bodies, TGA (Australia), Health Canada, or PMDA (Japan) — to accelerate or simplify its own review of medical devices. Rather than conducting an independent full technical evaluation, the NRA relies on the decision already made by a trusted reference authority, reducing duplication and enabling faster market access.

This report covers **146 markets** — 134 sovereign countries plus 12 regional and global regulatory frameworks. For each market, we assessed: (1) whether a formal or de facto reliance pathway exists, (2) a description of the pathway's nature and scope, and (3) whether a Free Sale Certificate (FSC) from the country of origin is required as part of the submission.

Key Findings

EU/EEA Bloc (31 markets)

EU27 + Norway, Iceland, Liechtenstein, Switzerland: YES pathway. CE marking via a Notified Body IS the authorization — no FSC required. Switzerland applies its own MedDO but recognizes CE marking.

GCC Bloc (6 markets)

Saudi Arabia, UAE, Qatar, Bahrain, Kuwait, Oman: YES pathway. These Gulf states rely on FDA/CE/reference approvals but FSC is required as part of the regulatory dossier.

EAEU Bloc (5 markets)

Russia, Belarus, Kazakhstan, Kyrgyzstan, Armenia: YES pathway via unified EAEU registration. FSC required. A device registered in one member state gains recognition across the union.

Conflict / Restricted Zones (4 markets)

Syria, Yemen, Afghanistan, Cuba: NO structured reliance pathway. These markets have limited or non-functional regulatory capacity for medical device oversight.

Africa & Central America (many markets)

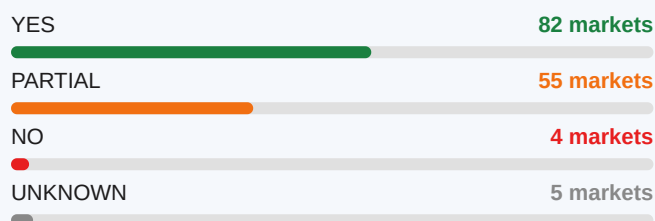
Mostly PARTIAL — regulatory systems are developing. CE or FDA approval may be considered informally, but no binding reliance programs are documented. FSC often required case-by-case.

Asia-Pacific Leaders

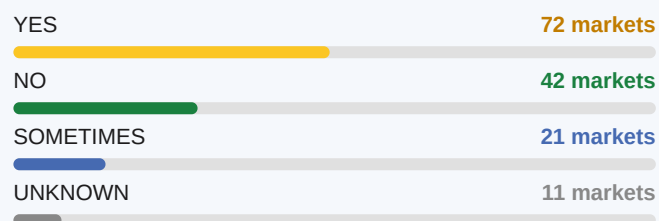
Australia (TGA), Japan (PMDA), South Korea (MFDS), Singapore (HSA): YES, mature reliance pathways. Australia and Singapore explicitly waive FSC; Japan and Korea have their own requirements.

Distribution Summary

Q1: Reliance Pathway Exists



Q3: FSC Required





Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Afghanistan	NO	Afghanistan has no formal medical device regulatory framework or reliance pathway. The Ministry of Public Health has limited capacity for medical device oversight, and no structured reliance on reference agencies has been documented.	UNKNOWN	MEDIUM
Albania	PARTIAL	Albania is an EU candidate country and has partially aligned its medical device regulatory framework with the EU MDR. Devices with valid CE marking are generally accepted, but Albania has not yet fully transposed EU MDR into national law. A structured reliance pathway exists de facto for CE-marked devices.	SOMETIMES	MEDIUM
Algeria	PARTIAL	Algeria's Ministry of Health regulates medical devices through the Directorate of Pharmacy and Equipment. A limited reliance pathway exists where CE marking or FDA clearance may be considered, but Algeria does not have a formal, documented reliance program. Registration is largely manual and case-by-case.	YES	MEDIUM
Argentina	YES	ANMAT (Argentina's national regulatory authority) operates a formal reliance pathway where devices approved by reference agencies (FDA, CE, Health Canada, ANVISA, TGA) can receive expedited registration. Class III devices with prior approval from reference agencies qualify for an abbreviated review. FSC is typically required as part of the dossier.	YES	HIGH
Armenia	YES	Armenia is a member of the Eurasian Economic Union (EAEU), which has a unified medical device registration system administered through the Eurasian Commission. Devices registered in one EAEU member state are recognized across the union under the EAEU common market rules. The system allows reliance on registration data from member states.	YES	HIGH
Australia	YES	The Therapeutic Goods Administration (TGA) operates a formal reliance pathway allowing manufacturers to use data from FDA, EMA/EU, Health Canada, PMDA Japan, and other reference agencies for expedited ARTG registration. Australia is also a founding member of IMDRF and participates in MDSAP. No separate FSC is required as TGA directly references foreign regulatory approvals.	NO	HIGH
Austria	YES	Austria is an EU member state and fully applies the EU Medical Device Regulation (MDR 2017/745) and IVDR (2017/746). CE marking by a Notified Body is the standard pathway; no separate national approval is required for CE-marked devices. Austrian competent authority (BASG) participates in EU regulatory reliance and mutual recognition.	NO	HIGH
Azerbaijan	PARTIAL	Azerbaijan has a basic medical device registration system under the Ministry of Health. The country is not an EAEU member and has no formal bilateral reliance agreement, but CE-marked devices and those approved by reference agencies may be considered favorably during national review. A fully structured reliance pathway has not been formally documented.	YES	MEDIUM
Bahrain	YES	Bahrain's National Health Regulatory Authority (NHRA) applies a reliance-based approach, accepting FDA 510(k)/PMA clearance and CE marking as the primary basis for medical device registration. Bahrain also participates in the Gulf Cooperation Council (GCC) harmonized framework. The NHRA reviews technical dossiers with reliance on reference agency decisions.	YES	HIGH
Bangladesh	PARTIAL	Bangladesh's Directorate General of Drug Administration (DGDA) oversees medical devices under a framework that is evolving. A limited reliance pathway exists where CE marking or WHO prequalification may be considered, but Bangladesh lacks a formally documented reliance program. Registration requirements are largely manual.	YES	MEDIUM
Belarus	YES	Belarus is a member of the Eurasian Economic Union (EAEU) and applies the unified EAEU medical device registration system. Devices registered in one EAEU member state receive market access across all member states. The system is administered through the Eurasian Commission, allowing reliance on registration data from EAEU partners.	YES	HIGH



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Belgium	YES	Belgium is an EU member state fully applying the EU MDR (2017/745) and IVDR (2017/746). CE marking is the sole authorization pathway for medical devices; no separate Belgian national approval is needed. FAMHP (Federal Agency for Medicines and Health Products) is the competent authority.	NO	HIGH
Belize	PARTIAL	Belize has a basic medicines regulatory authority but no dedicated medical device law or formal reliance pathway. In practice, CE marking or FDA clearance is used to support import decisions. No structured reliance program has been documented.	SOMETIMES	LOW
Benin	UNKNOWN	Benin has limited medical device regulatory capacity. No formal reliance pathway for medical devices has been documented. The country relies on WHO guidance and import controls, but a structured national system is not established.	UNKNOWN	LOW
Bolivia	PARTIAL	Bolivia's AGEMED (Agencia Estatal de Medicamentos y Tecnologías en Salud) regulates medical devices and accepts reliance on FDA or CE-marked devices for certain product categories, particularly in simplified registration tracks. The reliance pathway is not fully formalized but is applied in practice.	YES	MEDIUM
Bosnia and Herzegovina	PARTIAL	Bosnia and Herzegovina is an EU candidate country. The Agency for Medicinal Products and Medical Devices (ALMBIH) accepts CE-marked devices, effectively applying a reliance-based approach. National legislation is partially aligned with EU MDR, and CE marking is the practical standard for market entry.	SOMETIMES	MEDIUM
Botswana	PARTIAL	Botswana's Ministry of Health and Medicines Regulatory Authority has a basic medical device registration framework. CE marking and WHO prequalification are considered supportive evidence, but a formal reliance pathway has not been established. Botswana participates in Southern African Development Community (SADC) harmonization efforts.	YES	LOW
Brazil	YES	ANVISA operates a formal reliance pathway (Resolução RDC) for medical devices approved by reference regulators including FDA, Health Canada, EU (CE marking), TGA, and Japan PMDA. Class III and IV devices with prior reference agency approval qualify for an expedited registration track. Brazil is an IMDRF founding member and an active promoter of reliance.	YES	HIGH
Bulgaria	YES	Bulgaria is an EU member state and applies EU MDR (2017/745) and IVDR (2017/746). CE marking provides full market access. The Bulgarian Drug Agency (BDA) serves as the competent authority. No separate national device authorization is required for CE-marked devices.	NO	HIGH
Cambodia	PARTIAL	Cambodia's Department of Drug and Food (DDF) regulates medical devices under a developing framework. As an ASEAN member, Cambodia is working toward alignment with the ASEAN Medical Device Directive (AMDD). In practice, WHO prequalification, CE marking, or FDA clearance may expedite registration, but a formal reliance pathway is not fully codified.	YES	MEDIUM
Cameroon	PARTIAL	Cameroon has a limited medical device regulatory framework under the Ministry of Health. No formal reliance pathway exists, but CE marking and WHO prequalification are given weight during import review. Cameroon participates in ECOWAS harmonization discussions but has not fully implemented a reliance system.	YES	LOW
Canada	YES	Health Canada operates a formal Regulatory Cooperation Program and accepts foreign regulatory data from FDA, TGA, EMA, and other IMDRF members as part of its Abbreviated Regulatory Submission pathway. Canada is a founding member of IMDRF and MDSAP, and recognizes MDSAP audit reports in lieu of domestic audits. CE marking and FDA clearance data can support Canadian applications.	NO	HIGH



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Chile	YES	Chile's ISP (Instituto de Salud Pública) / ANAMED operates a reliance pathway for medical devices, accepting prior approvals from FDA, CE (EU), TGA, Health Canada, and ANVISA as a basis for expedited national registration. Chile has been an active participant in PAHO reliance initiatives and has formal reliance regulations in place.	YES	HIGH
China	PARTIAL	China's NMPA (National Medical Products Administration) does not operate a traditional reliance pathway; it conducts an independent technical review. However, China has an Innovative Medical Device Special Review pathway (fast track) and accepts some international data in technical submissions. For priority/innovative devices, prior international approvals can accelerate review but do not constitute formal reliance.	YES	HIGH
Colombia	YES	INVIMA (Instituto Nacional de Vigilancia de Medicamentos y Alimentos) operates a reliance pathway for medical devices, recognizing approvals from reference agencies including FDA, CE (EU), Health Canada, and ANVISA. Devices with prior reference agency approval may qualify for an expedited registration track. Colombia actively promotes reliance through PAHO networks.	YES	HIGH
Costa Rica	PARTIAL	Costa Rica's DCFD (Dirección de Control de Calidad y Farmacovigilancia) under the Ministry of Health regulates medical devices. A partial reliance pathway exists where FDA clearance or CE marking may support national registration. A fully formal reliance program has not been established, but reference approvals are factored into risk classification reviews.	YES	MEDIUM
Croatia	YES	Croatia is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization; no separate Croatian approval is needed. HALMED (Agency for Medicinal Products and Medical Devices) is the competent authority.	NO	HIGH
Cuba	NO	Cuba's CECMED regulates medical devices but operates a fully independent national approval system. Due to trade restrictions and the country's unique regulatory environment, no formal reliance pathway on international reference agencies has been established. All devices require full domestic review.	UNKNOWN	MEDIUM
Cyprus	YES	Cyprus is an EU member state and applies EU MDR (2017/745) and IVDR. CE marking is the sole authorization required for market access. The Ministry of Health serves as the competent authority for medical devices.	NO	HIGH
Czech Republic	YES	The Czech Republic is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. SÚKL (State Institute for Drug Control) serves as the competent authority for medical devices.	NO	HIGH
Côte d'Ivoire	PARTIAL	Côte d'Ivoire has a developing medical device regulatory framework under the Ministry of Health. No formal reliance pathway exists, but CE marking is used as a quality signal for import decisions. The country participates in ECOWAS regional harmonization efforts, which are still under development.	YES	LOW
Denmark	YES	Denmark is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization pathway. The Danish Medicines Agency (DKMA) serves as the national competent authority.	NO	HIGH
Dominican Republic	PARTIAL	The Dominican Republic's SESPAS/DIGEMAPS regulates medical devices. A partial reliance pathway exists where FDA clearance or CE marking may expedite the registration process. No fully formalized reliance system has been documented, but reference approvals are considered during review.	YES	MEDIUM



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Ecuador	PARTIAL	Ecuador's ARCSA (Agencia de Regulación y Control Sanitario) regulates medical devices. A partial reliance pathway exists where devices with FDA, CE, or ANVISA approval may receive expedited registration under certain product categories. A fully formal reliance program has not been codified but reference approvals are considered.	YES	MEDIUM
Egypt	YES	Egypt's Egyptian Drug Authority (EDA/EMDB - Egyptian Medical Devices Board) operates a reliance pathway that accepts FDA and CE-marked device approvals to support national registration. The EMDB expedited pathway for internationally approved devices allows for reduced technical review when a reference agency approval is provided. FSC is required as part of the submission.	YES	HIGH
El Salvador	PARTIAL	El Salvador's MINSAL (Ministerio de Salud) regulates medical devices with limited capacity. Reference approvals such as FDA clearance or CE marking are considered during import authorization and registration. A formal, documented reliance pathway has not been established, but foreign approvals are factored into review processes.	YES	LOW
Estonia	YES	Estonia is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. The State Agency of Medicines (Ravimiamet) serves as the competent authority for medical devices.	NO	HIGH
Eswatini	PARTIAL	Eswatini has a basic medicines regulatory authority under the Ministry of Health. No formal medical device reliance pathway exists, but CE marking and WHO prequalification are considered in import decisions. The country participates in SADC harmonization efforts at a preliminary stage.	YES	LOW
Ethiopia	PARTIAL	Ethiopia's Ethiopian Food and Drug Authority (EFDA) has established a medical device regulatory framework that includes consideration of WHO prequalification and international approvals. A partial reliance pathway exists where CE marking or FDA approval can support national registration, particularly for essential medical devices. Full reliance formalization is still in progress.	YES	MEDIUM
Finland	YES	Finland is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization pathway. FIMEA (Finnish Medicines Agency) serves as the competent authority for medical devices in Finland.	NO	HIGH
France	YES	France is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. ANSM (Agence Nationale de Sécurité du Médicament) serves as the French competent authority. France hosts several leading EU Notified Bodies.	NO	HIGH
Georgia	PARTIAL	Georgia's National Agency for Pharmacy and Medical Technology (NAPTM) regulates medical devices. Georgia has an EU Association Agreement and is partially aligning its regulatory framework with EU MDR. CE-marked devices are generally accepted, but a formal national reliance pathway has not been fully codified.	SOMETIMES	MEDIUM
Germany	YES	Germany is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. BfArM (Bundesinstitut für Arzneimittel und Medizinprodukte) and ZLG serve as competent authorities. Germany hosts major EU Notified Bodies (TÜV, BSI Germany).	NO	HIGH
Ghana	YES	Ghana's FDA (Food and Drugs Authority) operates a reliance pathway for medical devices, accepting WHO prequalification, CE marking, and FDA (US) clearance as supporting evidence for expedited registration. Ghana is an active participant in ECOWAS harmonization efforts and has worked to build reliance capacity with WHO and IMDRF support.	YES	HIGH



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Greece	YES	Greece is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. EOF (National Organization for Medicines) serves as the competent authority for medical devices in Greece.	NO	HIGH
Guatemala	PARTIAL	Guatemala's MSPAS and INAB regulate medical devices with limited capacity. FDA clearance or CE marking may support import authorization and registration on a case-by-case basis. A formal, documented reliance pathway has not been established, but foreign approvals are commonly referenced in the review process.	YES	LOW
Guyana	PARTIAL	Guyana's Ministry of Public Health has limited medical device regulatory infrastructure. No formal reliance pathway has been documented. FDA clearance and CE marking are used informally to support import decisions. Guyana is a CARICOM member but medical device harmonization at the regional level remains developing.	SOMETIMES	LOW
Honduras	PARTIAL	Honduras's SESAL (Secretaría de Salud) and ARSA (Agencia de Regulación Sanitaria) oversee medical device registration. Reference approvals such as FDA clearance or CE marking are considered supportive, but Honduras has not formally codified a reliance pathway. Registration relies heavily on manufacturer-submitted dossiers.	YES	LOW
Hong Kong	YES	Hong Kong's Medical Device Control Office (MDCO) under the Department of Health operates a formal reliance pathway. Devices with prior approval from FDA, EU CE, TGA, Health Canada, or Japan PMDA are eligible for an expedited registration track. Hong Kong's system closely follows IMDRF principles and is one of the most transparent reliance systems in Asia.	NO	HIGH
Hungary	YES	Hungary is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. OGYÉI (National Institute of Pharmacy and Nutrition) serves as the competent authority for medical devices.	NO	HIGH
Iceland	YES	Iceland is a member of the European Economic Area (EEA) and applies EU MDR (2017/745) and IVDR (2017/746) through the EEA Agreement. CE marking provides full market access in Iceland. The Icelandic Medicines Agency (IMA) serves as the competent authority.	NO	HIGH
India	YES	India's CDSCO (Central Drugs Standard Control Organisation) operates a reliance pathway under the Medical Device Rules 2017, allowing devices with prior approval from reference countries (USA, UK, EU, Australia, Japan, Canada) to apply for an Import License with abridged review. Class C and D devices with foreign approvals qualify for expedited registration under the abbreviated pathway.	YES	HIGH
Indonesia	YES	Indonesia's BPOM (Badan Pengawas Obat dan Makanan) operates a reliance pathway for medical devices, accepting WHO prequalification and prior approvals from FDA, EU, TGA, and Health Canada as supporting evidence. Indonesia is an ASEAN member working toward AMDD alignment, and BPOM has formal regulations allowing expedited review for internationally approved devices.	YES	HIGH
Iraq (Baghdad)	PARTIAL	Iraq's Central Drug Control Authority under the Ministry of Health regulates medical devices. A limited reliance pathway exists where CE marking or FDA clearance may support national registration. However, the regulatory system has limited capacity and a formally documented reliance program has not been established. Market access relies heavily on import controls.	YES	MEDIUM
Iraq (Kurdistan)	PARTIAL	The Kurdistan Region of Iraq has its own health ministry and regulatory oversight, which broadly follows the framework of the Iraqi central authority but operates with more autonomy. CE marking and FDA clearance are considered supportive for import approvals. No independently formal reliance pathway has been documented at the regional level.	YES	LOW



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Ireland	YES	Ireland is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. HPRA (Health Products Regulatory Authority) serves as the competent authority and hosts EU Notified Body-designated functions.	NO	HIGH
Israel	YES	Israel's MOH (Ministry of Health) Medical Devices Unit operates a formal reliance pathway accepting FDA, CE (EU), and Health Canada approvals as the basis for national registration. The Israeli system allows manufacturers to submit simplified dossiers based on reference agency decisions. Israel is known for its transparent, reliance-based device registration system.	NO	HIGH
Italy	YES	Italy is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. AIFA (Agenzia Italiana del Farmaco) and the Ministry of Health oversee medical device regulation. Italy hosts major EU Notified Bodies.	NO	HIGH
Jamaica	PARTIAL	Jamaica's Ministry of Health regulates medical devices through the National Health Fund and Pharmacy Council. No formal reliance pathway has been documented. FDA clearance or CE marking may support import decisions on a case-by-case basis. Jamaica is a CARICOM member but medical device harmonization at the regional level remains developing.	SOMETIMES	LOW
Japan	YES	Japan's PMDA (Pharmaceuticals and Medical Devices Agency) participates in IMDRF and MDSAP and has a foreign manufacturer registration system. Japan recognizes MDSAP audit reports in lieu of domestic QMS audits. Japan also has bilateral cooperation with FDA and EMA. While Japan conducts independent technical review, international clinical data and foreign approval data are formally accepted as supporting evidence.	SOMETIMES	HIGH
Jordan	YES	Jordan's JFDA (Jordan Food and Drug Administration) operates a reliance pathway accepting CE marking, FDA 510(k)/PMA, and approvals from other recognized regulatory bodies as a basis for expedited national registration. Jordan has one of the more developed reliance systems in the Middle East, with formal guidelines published for reference agency-based submissions.	YES	HIGH
Kazakhstan	YES	Kazakhstan is a founding member of the Eurasian Economic Union (EAEU) and applies the unified EAEU medical device registration system. Devices registered within EAEU member states have mutual market access. Kazakhstan also has national requirements for localization of some device categories, but the EAEU registration pathway is the primary reliance mechanism.	YES	HIGH
Kenya	YES	Kenya's Pharmacy and Poisons Board (PPB) / Kenya Medical Devices Regulatory Framework operates a reliance pathway accepting WHO prequalification, CE marking, and approvals from FDA and other reference agencies to support expedited national registration. Kenya is an active participant in EAC harmonization and is recognized as a relatively advanced African regulator for medical devices.	YES	HIGH
Kosovo	PARTIAL	Kosovo's Agency for Medicines and Medical Devices of Kosovo (AMMDK) oversees medical device regulation. Kosovo aspires to EU alignment and effectively uses CE marking as the de facto standard. A formal national reliance pathway has not been codified, but CE-marked devices are the practical standard for market entry.	SOMETIMES	LOW
Kuwait	YES	Kuwait's Ministry of Health regulates medical devices with a reliance-based approach, accepting CE marking and FDA clearance/approval as the primary basis for national registration. Kuwait participates in the GCC harmonized framework and follows GCC guidelines for medical device registration, which incorporate reliance on reference agency decisions.	YES	HIGH
Kyrgyzstan	YES	Kyrgyzstan is a member of the Eurasian Economic Union (EAEU) and applies the unified EAEU medical device registration system. Devices registered in one EAEU member state receive market access across the union. The EAEU unified registration is the primary reliance pathway available for the Kyrgyz market.	YES	HIGH



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Laos	PARTIAL	Laos's Food and Drug Department (FDD) under the Ministry of Health regulates medical devices. As an ASEAN member, Laos is working toward AMDD alignment, but implementation is at an early stage. CE marking and WHO prequalification may support import authorizations, but a formal reliance pathway has not been codified.	YES	LOW
Latvia	YES	Latvia is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization pathway. The State Agency of Medicines of Latvia (ZVA) serves as the competent authority for medical devices.	NO	HIGH
Lebanon	PARTIAL	Lebanon's Ministry of Public Health (MoPH) Medical Devices Division regulates medical devices. CE marking and FDA clearance are accepted as supporting evidence for registration, and a partial reliance pathway is applied in practice. However, Lebanon has not formally documented a structured national reliance program, and the regulatory system has faced challenges due to the country's economic situation.	YES	MEDIUM
Liechtenstein	YES	Liechtenstein is a member of the European Economic Area (EEA) and applies EU MDR (2017/745) and IVDR (2017/746) through the EEA Agreement. CE marking provides full market access. The Liechtenstein Office of Health (Amt für Gesundheit) serves as the competent authority.	NO	HIGH
Lithuania	YES	Lithuania is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. The State Medicines Control Agency (VVK) serves as the competent authority for medical devices in Lithuania.	NO	HIGH
Luxembourg	YES	Luxembourg is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. The Division of Pharmacy and Medicines (Direction de la Santé) serves as the competent authority.	NO	HIGH
Malaysia	YES	Malaysia's Medical Device Authority (MDA) operates a formal reliance pathway. Devices approved by reference agencies (FDA, CE, TGA, Health Canada, PMDA Japan, MFDS Korea) can be registered through an expedited pathway with abridged technical review. Malaysia has been implementing a tiered reliance system and is an active ASEAN AMDD participant.	YES	HIGH
Maldives	UNKNOWN	The Maldives Food and Drug Authority (MFDA) has limited medical device regulatory capacity. No formal reliance pathway for medical devices has been documented. Import decisions are largely based on WHO guidance and international standards, but no structured national reliance system exists.	UNKNOWN	LOW
Malta	YES	Malta is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. The Medicines Authority (MA) serves as the competent authority for medical devices in Malta.	NO	HIGH
Mauritius	PARTIAL	Mauritius's Ministry of Health and the newly established regulatory authority are developing a medical device framework. CE marking and WHO standards are used as reference points for import decisions. Mauritius is working toward a more formalized regulatory system but no fully documented reliance pathway has been established.	YES	LOW
Mexico	YES	COFEPRIS (now COFEMED) operates a formal fast-track pathway for medical devices approved by reference agencies including FDA, Health Canada, CE (EU), TGA, and ANVISA. The Innovative Sanitary Registration pathway allows expedited review with abridged technical documentation for devices with prior approval from listed reference agencies. Mexico is an IMDRF observer.	YES	HIGH



Country Regulatory Reliance Data

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Moldova	PARTIAL	Moldova's Agency for Medicines and Medical Devices (AMDM) regulates medical devices. Moldova has an EU Association Agreement and is progressively aligning with EU MDR. CE-marked devices are generally accepted, and a partial reliance pathway exists in practice, though a fully formal national reliance program has not been codified.	SOMETIMES	MEDIUM
Mongolia	PARTIAL	Mongolia's Agency for Standardization and Metrology and the Ministry of Health oversee medical device imports. A partial reliance approach exists where CE marking and WHO standards are referenced, but Mongolia has not established a formal, documented reliance pathway. Registration decisions rely heavily on manufacturer-submitted technical documentation.	YES	LOW
Montenegro	PARTIAL	Montenegro is an EU candidate country. The Agency for Medicines and Medical Devices of Montenegro (CALIMS) accepts CE-marked devices, effectively applying an EU reliance approach. The national framework is being aligned with EU MDR, and CE marking is the de facto standard for market entry.	SOMETIMES	MEDIUM
Morocco	PARTIAL	Morocco's Ministry of Health and its pharmaceutical regulatory division oversee medical devices. CE marking is commonly used as a quality reference, and a partial reliance pathway exists for CE-marked devices. Morocco does not have a fully formalized, documented reliance program but is developing its regulatory framework with EU influence.	YES	MEDIUM
Myanmar	PARTIAL	Myanmar's Food and Drug Administration (FDA Myanmar) has a developing medical device regulatory framework. As an ASEAN member, Myanmar is working toward AMDD alignment at an early stage. CE marking and WHO standards may support import decisions but no formally documented reliance pathway exists.	YES	LOW
Namibia	PARTIAL	Namibia's Medicines Regulatory Council (MRC) is developing medical device oversight capacity. CE marking and WHO prequalification are referenced for import decisions. Namibia participates in SADC harmonization efforts. No fully codified national reliance pathway has been documented.	YES	LOW
Netherlands	YES	The Netherlands is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. The IGJ (Inspectie Gezondheidszorg en Jeugd) serves as the competent authority. The Netherlands hosts several major EU Notified Bodies.	NO	HIGH
New Zealand	YES	Medsafe (New Zealand Medicines and Medical Devices Safety Authority) operates a reliance-based system for medical devices, accepting approvals from FDA, TGA, Health Canada, EU (CE marking), and PMDA Japan as the basis for expedited national registration. New Zealand has been deepening regulatory cooperation with Australia (TGA) and is an IMDRF member.	NO	HIGH
Nicaragua	PARTIAL	Nicaragua's MINSA (Ministerio de Salud) has limited medical device regulatory capacity. FDA clearance or CE marking may be considered supportive for import authorization, but no formal documented reliance pathway has been established. Registration is based on submitted technical documentation.	YES	LOW
Nigeria	YES	Nigeria's NAFDAC (National Agency for Food and Drug Administration and Control) operates a reliance pathway for medical devices, accepting WHO prequalification, CE marking, and FDA approval as supporting evidence for expedited registration. NAFDAC has formally published reliance guidelines and is one of the more advanced African regulators for medical devices.	YES	HIGH
North Macedonia	PARTIAL	North Macedonia is an EU candidate country. The Agency for Medicines and Medical Devices of Macedonia (MALMED) accepts CE-marked devices, applying a de facto EU reliance approach. The national framework is being aligned with EU MDR, and CE marking is the practical standard for market entry.	SOMETIMES	MEDIUM



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Norway	YES	Norway is a member of the European Economic Area (EEA) and applies EU MDR (2017/745) and IVDR (2017/746) through the EEA Agreement. CE marking provides full market access in Norway. The Norwegian Medicines Agency (NoMA) serves as the competent authority for medical devices.	NO	HIGH
Oman	YES	Oman's Ministry of Health regulates medical devices with a reliance-based approach, accepting CE marking and FDA clearance/approval as the primary basis for national registration. Oman participates in the GCC harmonized framework and follows GCC guidelines for medical device registration. FSC is required as part of the registration dossier.	YES	HIGH
Pakistan	PARTIAL	Pakistan's DRAP (Drug Regulatory Authority of Pakistan) has enacted the Medical Devices Rules 2017, which allows for a reliance-based approach for certain device categories with prior CE marking or WHO prequalification. However, implementation is still developing, and the reliance pathway is only partially operationalized for a limited set of device types.	YES	MEDIUM
Palestine	PARTIAL	The Palestinian Ministry of Health has limited medical device regulatory capacity. CE marking and WHO standards are used as reference points for import decisions, but no formal reliance pathway has been documented. The regulatory system operates under significant constraints.	YES	LOW
Panama	PARTIAL	Panama's MINSA and DRP (Dirección de Regulación de Productos Farmacéuticos) regulate medical devices. FDA clearance or CE marking may support registration applications on a case-by-case basis. Panama has not established a fully formalized reliance pathway, but reference approvals are commonly used to support dossiers.	YES	MEDIUM
Paraguay	PARTIAL	Paraguay's DINAVISA (Dirección Nacional de Vigilancia Sanitaria) regulates medical devices. Reference agency approvals such as CE marking or FDA clearance are considered in registration applications. Paraguay has not formally codified a reliance pathway, but is developing its regulatory framework with PAHO guidance.	YES	LOW
Peru	YES	Peru's DIGEMID (Dirección General de Medicamentos, Insumos y Drogas) operates a reliance pathway for medical devices, accepting FDA, CE (EU), TGA, Health Canada, ANVISA, and INVIMA approvals as a basis for expedited national registration. Peru has formalized its reliance approach and is active in PAHO harmonization networks.	YES	HIGH
Philippines	YES	The Philippines FDA (Food and Drug Administration) operates a formal reliance pathway, accepting prior approvals from FDA (USA), CE (EU), TGA, Health Canada, and Japan PMDA as supporting evidence for expedited Certificate of Product Registration. The Philippines is an ASEAN member actively implementing AMDD alignment. A Certificate of Free Sale is required from the country of origin.	YES	HIGH
Poland	YES	Poland is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. URPL (Office for Registration of Medicinal Products, Medical Devices and Biocidal Products) serves as the competent authority.	NO	HIGH
Portugal	YES	Portugal is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. INFARMED (National Authority of Medicines and Health Products) serves as the competent authority for medical devices.	NO	HIGH
Puerto Rico	YES	Puerto Rico is a US territory and fully subject to FDA regulation (21 CFR Parts 800-898). Medical devices marketed in Puerto Rico must have FDA 510(k) clearance, PMA approval, or De Novo authorization, just as for the US mainland. No separate Puerto Rico registration is required.	NO	HIGH



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Qatar	YES	Qatar's Ministry of Public Health (MoPH) regulates medical devices with a reliance-based approach, accepting CE marking, FDA, and other reference agency approvals as the primary basis for national registration. Qatar follows GCC harmonized guidelines and has a formal device registration process with reliance provisions. FSC is required as part of the submission.	YES	HIGH
Republic of Serbia	YES	Serbia's ALIMs (Agency for Medicines and Medical Devices of Serbia) operates a reliance pathway that closely follows EU MDR. Serbia is an EU candidate country and accepts CE-marked devices under a de facto reliance approach. Serbian law has been substantially aligned with EU MDR, and CE marking is the primary basis for national registration.	SOMETIMES	HIGH
Romania	YES	Romania is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. ANMDMR (National Agency for Medicines and Medical Devices of Romania) serves as the competent authority.	NO	HIGH
Russia	PARTIAL	Russia's Roszdravnadzor regulates medical devices through state registration, which involves a comprehensive independent review. Russia is an EAEU member and participates in EAEU unified registration for some device categories. However, Russia generally conducts a parallel national review and does not operate a full reliance pathway; foreign approvals may be submitted as supporting data but do not guarantee expedited registration.	YES	HIGH
Rwanda	PARTIAL	Rwanda's Rwanda Food and Drugs Authority (FDA Rwanda) has been developing its medical device regulatory framework with WHO and EAC support. A partial reliance pathway exists where WHO prequalification and approvals from major reference agencies are considered. Rwanda is one of the more reform-minded African regulatory agencies.	YES	MEDIUM
Saudi Arabia	YES	Saudi Arabia's SFDA (Saudi Food and Drug Authority) operates a comprehensive reliance pathway for medical devices. The SFDA accepts prior approvals from FDA, CE (EU), Health Canada, TGA, PMDA Japan, MFDS Korea, and other GCC regulators as supporting evidence for national registration. SFDA has a tiered reliance system with different requirements based on risk class and reference agency. FSC is required.	YES	HIGH
Senegal	PARTIAL	Senegal's Directorate of Pharmacy and Drugs has a basic medical device framework. No formal reliance pathway has been documented, but CE marking and WHO prequalification are used as quality references for import decisions. Senegal participates in ECOWAS harmonization efforts which are still developing.	YES	LOW
Singapore	YES	Singapore's HSA (Health Sciences Authority) operates a formal reliance pathway for medical devices. Devices with prior approval from FDA, EU (CE marking), TGA, Health Canada, or Japan PMDA are eligible for a Product Listing via reliance, with significantly reduced review timelines. Singapore is an IMDRF member and one of the leading reliance-implementing regulators in Asia.	NO	HIGH
Slovakia	YES	Slovakia is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. ŠÚKL (State Institute for Drug Control Slovakia) serves as the competent authority for medical devices.	NO	HIGH
Slovenia	YES	Slovenia is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. JAZMP (Agency for Medicinal Products and Medical Devices of the Republic of Slovenia) serves as the competent authority.	NO	HIGH
South Africa	YES	South Africa's SAHPRA (South African Health Products Regulatory Authority) operates a formal reliance pathway for medical devices under Section 21 of the Medicines and Related Substances Act. SAHPRA accepts decisions from reference agencies (FDA, EMA, Health Canada, TGA) for expedited registration. SAHPRA has a published reliance policy and is one of the most capable regulatory authorities in Africa.	YES	HIGH



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
South Korea	YES	South Korea's MFDS (Ministry of Food and Drug Safety) is an IMDRF member and MDSAP participating country. MFDS recognizes MDSAP audit reports and participates in bilateral regulatory cooperation with FDA, TGA, and the EU. Korea has an abbreviated review pathway for devices with prior approval from recognized reference agencies. FSC is required for imported devices.	YES	HIGH
Spain	YES	Spain is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. AEMPS (Agencia Española de Medicamentos y Productos Sanitarios) serves as the competent authority for medical devices.	NO	HIGH
Sri Lanka	PARTIAL	Sri Lanka's NMRA (National Medicines Regulatory Authority) has a developing medical device framework. CE marking and WHO prequalification are referenced for import decisions. A partial reliance approach exists, but a fully formalized reliance pathway for medical devices has not been codified. The NMRA has been expanding its medical device oversight capacity.	YES	MEDIUM
Sudan	UNKNOWN	Sudan's Federal Ministry of Health has limited medical device regulatory infrastructure, compounded by ongoing conflicts. No formal reliance pathway has been documented. Import control relies on basic customs checks and WHO guidance, but no structured regulatory review system is operational.	UNKNOWN	LOW
Suriname	UNKNOWN	Suriname has very limited medical device regulatory infrastructure. The Bureau for Public Health has authority over medicines but a formal medical device registration system with a reliance pathway has not been documented. Import decisions may reference FDA or CE marking informally.	UNKNOWN	LOW
Sweden	YES	Sweden is an EU member state and fully applies EU MDR (2017/745) and IVDR (2017/746). CE marking is the required authorization. MPA (Läkemedelsverket / Medical Products Agency) serves as the competent authority for medical devices in Sweden.	NO	HIGH
Switzerland	YES	Switzerland's Swissmedic regulates medical devices and, through the bilateral Switzerland-EU Mutual Recognition Agreement (MRA) on medical devices, aligns its framework with EU MDR. CE marking by an EU Notified Body is accepted for Swiss market access. Swissmedic has implemented the Medical Devices Ordinance (MedDO) aligned with EU MDR 2017/745.	NO	HIGH
Syria	NO	Syria's regulatory system for medical devices is severely disrupted due to ongoing conflict. The Ministry of Health has very limited capacity for medical device oversight. No formal reliance pathway exists, and regulatory review is not systematically conducted.	UNKNOWN	LOW
Taiwan	YES	Taiwan's TFDA (Taiwan Food and Drug Administration) operates a formal reliance pathway for medical devices. Devices with prior FDA 510(k)/PMA or CE marking approval may qualify for a simplified registration track with abridged technical review. Taiwan is an active IMDRF participant and has bilateral cooperation with FDA and other major regulators.	YES	HIGH
Tanzania	PARTIAL	Tanzania's TMDA (Tanzania Medicines and Medical Devices Authority) has a developing medical device regulatory framework. A partial reliance pathway exists where WHO prequalification and approvals from reference agencies (FDA, CE) are considered for expedited registration. Tanzania participates in EAC harmonization efforts.	YES	MEDIUM
Thailand	YES	Thailand's FDA (Thai FDA - TFDA) operates a formal reliance pathway for medical devices under the Medical Device Act B.E. 2562. Devices with prior approval from FDA (USA), CE (EU), TGA, Health Canada, and PMDA Japan are eligible for a simplified registration track. Thailand is an ASEAN member actively implementing AMDD and publishes formal reliance guidelines.	YES	HIGH



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Tunisia	PARTIAL	Tunisia's DHMPE (Direction de l'Hygiène du Milieu et de la Protection de l'Environnement) under the Ministry of Health regulates medical devices. CE marking is used as the primary quality standard, and a partial reliance approach exists in practice. No formally codified national reliance pathway has been documented.	YES	MEDIUM
Turkey	YES	Turkey's TITCK (Turkish Medicines and Medical Devices Agency) operates a regulatory framework closely aligned with EU MDR under the Turkish Medical Devices Regulation (YUTEP). CE marking is a prerequisite for medical device registration in Turkey, effectively implementing a reliance approach on EU Notified Body certification. Turkey is a Customs Union member with the EU for goods.	SOMETIMES	HIGH
Turkmenistan	UNKNOWN	Turkmenistan has limited medical device regulatory transparency. No formal reliance pathway for medical devices has been documented. The Ministry of Health oversees drug and device imports, but no structured reliance system has been publicly described.	UNKNOWN	LOW
Uganda	PARTIAL	Uganda's NDA (National Drug Authority) has a developing medical device regulatory framework. A partial reliance pathway exists where WHO prequalification and approvals from reference agencies (FDA, CE) may support expedited registration. Uganda participates in EAC harmonization efforts. The NDA has been actively developing its medical device regulatory capacity.	YES	MEDIUM
Ukraine	YES	Ukraine's State Expert Centre under the Ministry of Health operates a reliance pathway for medical devices. As part of its EU Association Agreement, Ukraine has been aligning its framework with EU MDR. CE-marked devices are accepted through an expedited registration process. The regulatory system has continued to operate despite wartime conditions, maintaining a reliance-based approach.	SOMETIMES	HIGH
United Arab Emirates	YES	The UAE's MOHAP (Ministry of Health and Prevention) and Dubai DHA / Abu Dhabi DOH operate formal reliance pathways for medical devices. The system accepts FDA, CE (EU), TGA, and Health Canada approvals as the primary basis for national registration. The UAE has a tiered system based on device risk class and follows GCC harmonized guidelines. FSC is required for most registrations.	YES	HIGH
United Kingdom	YES	The UK's MHRA (Medicines and Healthcare products Regulatory Agency) has established the UKCA (UK Conformity Assessed) marking system post-Brexit, and currently accepts CE marking as a transitional measure. MHRA operates an Approved Body system and has bilateral cooperation with FDA and other IMDRF members. UK also has a Medical Device Single Audit Program (MDSAP) recognition pathway.	NO	HIGH
United States of America	YES	The FDA is an IMDRF founding member and co-leads international harmonization efforts. The FDA recognizes MDSAP audit reports in lieu of domestic QMS inspections and participates in bilateral reliance cooperation with TGA, Health Canada, PMDA, and others. The FDA's 510(k), PMA, and De Novo pathways are the world's most-referenced benchmarks for reliance-based registration globally.	NO	HIGH
Uruguay	YES	Uruguay's MSP (Ministerio de Salud Pública) / UFARMA operates a reliance pathway for medical devices, accepting FDA, CE (EU), ANVISA, and ANMAT approvals as supporting evidence for national registration. Uruguay actively participates in PAHO harmonization efforts and has formalized regulatory cooperation with Mercosur partners.	YES	HIGH
Venezuela	PARTIAL	Venezuela's INHRR (Instituto Nacional de Higiene Rafael Rangel) regulates medical devices. Due to the country's economic and political challenges, the regulatory system operates with limited capacity. Reference approvals (FDA, CE) may be submitted as supporting data, but a formally documented and operational reliance pathway has not been recently confirmed.	YES	LOW
Vietnam	YES	Vietnam's DAV (Drug Administration of Vietnam) under the Ministry of Health operates a formal reliance pathway for medical devices under Circular 30/2015/TT-BYT and subsequent regulations. Devices with prior approval from FDA, CE (EU), TGA, Health	YES	HIGH

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
		Canada, PMDA Japan, or MFDS Korea qualify for Class B/C/D expedited registration. Vietnam is an ASEAN member implementing AMDD alignment.		



Country Regulatory Reliance Data

Country	Q1: Pathway	Q2: Description	Q3: FSC	Confidence
Yemen	NO	Yemen's medical device regulatory system is not operational due to the ongoing armed conflict. The Ministry of Health has extremely limited capacity, and no structured regulatory review for medical devices is conducted. Import decisions are primarily humanitarian-driven.	UNKNOWN	LOW
Zimbabwe	PARTIAL	Zimbabwe's Medicines Control Authority of Zimbabwe (MCAZ) has a developing medical device framework. CE marking and WHO prequalification are referenced for import decisions. A partial reliance approach is applied in practice, but a fully codified national reliance pathway for medical devices has not been established. Zimbabwe participates in SADC harmonization efforts.	YES	MEDIUM

Regional & Global Frameworks

Bodies that don't represent a single country but influence multiple markets

ASEAN (Regional)

YES

ASEAN has established the ASEAN Medical Device Directive (AMDD) framework to harmonize medical device regulation across member states. The ASEAN Medical Device Product Database (AMDD) allows manufacturers to register once and seek recognition across member states. Reliance on ASEAN-listed devices and reference agency approvals (FDA, CE, TGA) is embedded in many member state frameworks.

FSC: **SOMETIMES**

Africa (Regional)

PARTIAL

The African Union's African Medicines Regulatory Harmonisation (AMRH) initiative and the African Medicines Agency (AMA) are developing a pan-African reliance framework for medical devices. Progress is uneven across sub-regions, with East Africa (EAC) and West Africa (ECOWAS) more advanced. Full implementation of continental harmonization remains in progress.

FSC: **SOMETIMES**

Americas (Regional)

PARTIAL

The Pan American Health Organization (PAHO) promotes regulatory reliance across the Americas through the Pan American Network for Drug Regulatory Harmonization (PANDRH) and its medical device working group. Several national regulators have adopted reliance frameworks inspired by PAHO guidance, but there is no single binding regional reliance pathway.

FSC: **SOMETIMES**

Asia-Pacific (Regional)

PARTIAL

APEC (Asia-Pacific Economic Cooperation) has promoted regulatory harmonization through the APEC Life Sciences Innovation Forum (LSIF). Several Asia-Pacific regulators participate in IMDRF and have adopted reliance principles, but there is no binding regional medical device reliance pathway. Individual country frameworks vary significantly.

FSC: **SOMETIMES**

Caribbean (Regional)

PARTIAL

The Caribbean Community (CARICOM) has a Caribbean Regulatory System (CRS) that covers medicines, with medical devices being under less developed regional harmonization. Individual island nations vary in their regulatory capacity; some rely on FDA or CE marking for import control, but no binding regional reliance framework for medical devices exists.

FSC: **SOMETIMES**

East Africa (Regional)

YES

The East African Community (EAC) has established the East African Health Research Commission and the EAC Medical Devices Guidelines to harmonize regulation across Kenya, Tanzania, Uganda, Rwanda, Burundi, and South Sudan. The framework promotes reliance on WHO prequalification and approved reference agency decisions. Implementation varies by member state.

FSC: **SOMETIMES**

Europe (Regional)

YES

The European Union's Medical Device Regulation (EU MDR 2017/745) and IVDR (2017/746) create a harmonized regulatory framework across 27 EU member states plus EEA countries (Norway, Iceland, Liechtenstein). Notified Body CE certification provides market access across all participating countries. The EU is an IMDRF founding member and has mutual recognition agreements with several countries.

FSC: **NO**

European Union

YES

The EU MDR (2017/745) and IVDR (2017/746) are the primary regulatory frameworks for medical devices across EU member states. CE marking by an EU Notified Body is required for market access. The EU participates in IMDRF and has bilateral reliance/recognition agreements with select countries. No FSC is required for devices with CE marking.

FSC: **NO**

Global

YES

The International Medical Device Regulators Forum (IMDRF) provides global frameworks for regulatory reliance and convergence, including the IMDRF Principles on Regulatory Reliance, the Table of Contents for Submissions, and MDSAP. The WHO's prequalification program and guidance documents also serve as global reliance reference points. These frameworks are adopted voluntarily by national regulators.

FSC: UNKNOWN

Gulf Region (Regional)

YES

The Gulf Cooperation Council (GCC) has established the Gulf Technical Regulation for Medical Devices (GHTF-based standards) and the GCC Drug Regulatory Authority (GCDRA) which harmonizes medical device regulation across Saudi Arabia, UAE, Qatar, Bahrain, Kuwait, and Oman. Member states individually require registration but the framework promotes reliance on FDA, CE, and other reference agencies.

FSC: YES

International

YES

IMDRF (International Medical Device Regulators Forum) provides the foundational principles for international regulatory reliance for medical devices. IMDRF documents such as the Principles on Regulatory Reliance, Common Submission Dossier Template (CSDT), and MDSAP are adopted by member regulators (FDA, TGA, Health Canada, PMDA, NMPA, ANVISA, MFDS, etc.) to reduce duplicative review.

FSC: UNKNOWN

Middle East (Regional)

PARTIAL

The Middle East lacks a unified regional medical device regulatory authority. The GCC countries (Saudi Arabia, UAE, Qatar, Bahrain, Kuwait, Oman) have the most developed reliance frameworks in the region. Other Middle Eastern countries (Jordan, Egypt, Lebanon, Iraq) have varying degrees of reliance-based registration. No binding pan-Middle East reliance framework exists.

FSC: SOMETIMES

