



REGDESK DATA INTELLIGENCE

Reliance Pathway Intelligence Report

Medical Device Market Access — Global Overview

Coverage: 134 Sovereign Countries & Territories + 12 Regional Bodies

Questions Answered: Q1 — Reliance Exists? | Q2 — Pathway Description | Q3 — FSC Required?

Date: July 08, 2026

69

Full Reliance Pathway

59

Partial Reliance

3

No Reliance Pathway

3

Unknown / Unclear



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Afghanistan	NRAA	UNKNOWN	Regulatory system largely non-functional. Under current governance, no formal reliance pathway is documented. Market access is largely informal.	UNKNOWN
Albania	AKPT	YES	EU accession candidate. CE Mark-certified devices accepted under Albania's EU alignment legislation, providing a de facto reliance pathway on EU MDR/IVDR.	YES
Algeria	Ministry of Health	PARTIAL	CE Mark is a mandatory prerequisite, but a separate local registration must still be completed. Foreign approvals serve as required supporting documentation only.	YES
Argentina	ANMAT	YES	ANMAT maintains an abbreviated registration pathway for devices approved by recognized reference agencies (FDA, CE Mark, TGA, Health Canada, PMDA, MFDS, HSA), providing significantly expedited review.	YES
Armenia	MOH / EAEU	PARTIAL	EAEU member. Devices registered via the EAEU unified procedure (primarily through Russia) are recognized across the union under TR EAEU 017/2011.	YES
Australia	TGA	YES	TGA offers an abridged conformity assessment pathway relying on CE Mark (EU Notified Bodies), FDA, and Health Canada. TGA is itself a globally recognized reference agency.	PARTIAL
Austria	BASG	YES	EU member state (EU MDR/IVDR). CE Mark issued by an EU Notified Body grants direct market access across all EU/EEA states — no separate national registration required.	NO
Azerbaijan	TABIB	PARTIAL	Foreign approvals (CE Mark, FDA) must be submitted as supporting documentation and may expedite review, but a formal reliance pathway is not codified in law.	YES
Bahrain	NHRA	YES	NHRA streamlined pathway for devices approved by reference agencies (FDA, CE Mark, TGA, SFDA). GCC harmonization facilitates mutual recognition.	YES
Bangladesh	DGDA	PARTIAL	FDA or CE Mark approval is a prerequisite but a full local registration is still required; limited formal reliance acceleration.	YES
Belarus	MOH / EAEU	PARTIAL	EAEU member. EAEU unified registration applies; Russian/EAEU approvals recognized across the union under TR EAEU 017/2011.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Belgium	FAMHP	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. FAMHP oversees market surveillance; no national approval required.	NO
Belize	MOH	PARTIAL	Very limited regulatory infrastructure. Foreign approvals (FDA, CE Mark) serve as supporting documentation; no formal reliance framework exists.	UNKNOWN
Benin	MOH / DIEM	PARTIAL	Import authorization required. CE Mark and FDA approvals are required supporting documentation. ECOWAS harmonization ongoing but formal reliance not codified.	YES
Bolivia	UNIMED	PARTIAL	Foreign approvals (FDA, CE Mark) are required documentation but do not substitute for local review. No formal abbreviated reliance pathway codified.	YES
Bosnia and Herzegovina	ALMBIH	YES	EU accession candidate. Regulations aligned with EU MDR/IVDR. CE Mark-approved devices accepted by ALMBIH — de facto reliance pathway.	YES
Botswana	BOMRA	PARTIAL	BOMRA gives significant weight to reference agency approvals (FDA, CE Mark, TGA, WHO PQ). Expedited pathway available in SADC context.	YES
Brazil	ANVISA	YES	ANVISA Regularizacao Simplificada for devices approved by reference agencies (FDA, EMA/CE Mark, Health Canada, TGA, PMDA, MFDS). ANVISA is itself a global reference agency.	YES
Bulgaria	BDA	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. Bulgarian Drug Agency oversees market surveillance.	NO
Cambodia	DDF	PARTIAL	DDF requires device registration with foreign approvals (FDA, CE Mark) as mandatory supporting documentation. ASEAN AMDD principles apply; formal reliance is limited.	YES
Cameroon	DPM	PARTIAL	Import authorization required. CE Mark and FDA approvals required as supporting documentation. Limited formal reliance; foreign approvals effectively prerequisite.	YES
Canada	Health Canada	YES	Health Canada maintains a reference country listing. Class III/IV devices from reference countries (US, EU, Australia, Japan) may benefit from reliance on prior approval.	NO



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Chile	ISP / ANAMED	YES	ANAMED has an abbreviated registration pathway for devices approved by reference agencies (FDA, CE Mark, TGA, ANVISA). Class III devices benefit most from expedited review.	YES
China	NMPA	NO	NMPA does not rely on foreign agency approvals. An independent Chinese registration is mandatory for all device classes, typically requiring Chinese clinical data, independent testing, and full technical review.	NO
Colombia	INVIMA	YES	INVIMA streamlined registration for devices approved by reference agencies (FDA, CE Mark, TGA, ANVISA, Health Canada, MFDS). Prior approval grants access to abbreviated technical review.	YES
Costa Rica	MINSA / DNFMDS	YES	MINSA accepts devices approved by recognized reference agencies (FDA, CE Mark, Health Canada, ANVISA) for an abbreviated registration process.	YES
Cote d'Ivoire	DPML	PARTIAL	Import authorization required. CE Mark and FDA approvals required as supporting documentation. ECOWAS harmonization context; no formal abbreviated pathway.	YES
Croatia	HALMED	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. HALMED oversees market surveillance.	NO
Cuba	CECMED	NO	CECMED conducts independent regulatory review. No formal reliance pathway on foreign approvals. Geopolitical constraints further restrict access to reference-agency approvals.	UNKNOWN
Cyprus	MoH Pharmaceutical Services	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. No separate national registration required.	NO
Czech Republic	SUKL	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. SUKL oversees market surveillance.	NO
Denmark	DKMA	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. DKMA oversees market surveillance.	NO
Dominican Republic	SESPAS / DIGEMAPS	PARTIAL	Foreign approvals (FDA, CE Mark) required as mandatory supporting documentation; local registration still required but foreign approval significantly supports the application.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Ecuador	ARCSA	PARTIAL	Local registration required. FDA and CE Mark approvals are mandatory supporting documentation. An expedited reliance pathway is being developed but not yet fully formalized.	YES
Egypt	GAfDA	PARTIAL	Full local registration required. CE Mark is effectively a prerequisite for higher-risk devices. A formal reliance pathway has been proposed but is not yet fully implemented.	YES
El Salvador	DNM / MSPAS	PARTIAL	COMISCA regional harmonization framework. Reference approvals (FDA, CE Mark) required as documentation. Full local registration required.	YES
Estonia	SAM	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. State Agency of Medicines oversees market surveillance.	NO
Eswatini	MOH	PARTIAL	Very limited regulatory capacity. CE Mark and WHO PQ approvals required as supporting documentation. SADC context; no formal abbreviated pathway.	YES
Ethiopia	EFDA	PARTIAL	EFDA requires device registration. CE Mark and FDA approvals are mandatory supporting documentation. EAC harmonization context; limited formal reliance acceleration.	YES
Finland	Fimea	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. Fimea oversees market surveillance.	NO
France	ANSM	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. ANSM oversees market surveillance and clinical investigations.	NO
Georgia	MEPA	PARTIAL	Under the EU-Georgia Association Agreement, CE Mark is increasingly recognized. MEPA is developing an abbreviated pathway for CE-marked devices but formal codification is still in progress.	YES
Germany	BfArM	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. Germany hosts several major EU Notified Bodies. BfArM oversees market surveillance.	NO
Ghana	FDA Ghana	PARTIAL	FDA Ghana requires device registration. CE Mark required as supporting documentation. ECOWAS harmonization context; no formal abbreviated pathway.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Greece	EOF	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. EOF oversees market surveillance.	NO
Guatemala	MSPAS	PARTIAL	COMISCA framework. Reference approvals (FDA, CE Mark) required as documentation. Limited formal reliance; local registration required.	YES
Guyana	MOH	PARTIAL	Very limited regulatory infrastructure. CE Mark and FDA approvals serve as required supporting documentation. CARICOM context; no formal reliance framework.	UNKNOWN
Honduras	ARSA	PARTIAL	COMISCA framework. Reference approvals (FDA, CE Mark) required as documentation. Limited regulatory infrastructure; local registration required.	YES
Hong Kong	MDCO / DH	YES	MDACS accepts devices approved by reference agencies (FDA, CE Mark, TGA, Health Canada, MFDS) under a voluntary notification system. Class IIb/III devices receive significantly streamlined registration.	NO
Hungary	OGYEI	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. OGYEI oversees market surveillance.	NO
Iceland	IMA	YES	EEA member state. EU MDR/IVDR applies via EEA Agreement. CE Mark grants full market access in Iceland without additional national registration.	NO
India	CDSCO	YES	CDSCO has an abbreviated notification pathway for Class A/B devices from reference countries (US, EU, Australia, Canada, Japan). Class C/D devices require full registration but reference approval is a significant supporting factor.	YES
Indonesia	BPOM	PARTIAL	BPOM accepts CE Mark and FDA approvals as key supporting documentation and may expedite review. A formal abbreviated pathway exists but a local Indonesian registration process is still required.	YES
Iraq (Baghdad)	MOH Iraq	PARTIAL	Iraq MOH requires device registration with CE Mark and FDA approvals as mandatory supporting documentation. Limited regulatory capacity; formal reliance mechanism not codified.	YES
Iraq (Kurdistan)	MOH Kurdistan Region	PARTIAL	Kurdistan Regional Government MOH oversees device import authorization. CE Mark and FDA approvals required. Operates semi-independently of Baghdad's regulatory system.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Ireland	HPRA	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. HPRA is an active EU competent authority.	NO
Israel	AMAR	YES	AMAR has a robust abbreviated pathway for devices approved by reference agencies (FDA, CE Mark, TGA, Health Canada). Prior approval from a reference agency is the primary basis for Israeli registration.	YES
Italy	Ministry of Health	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. Some devices require additional steps for national reimbursement listing.	NO
Jamaica	MOH	PARTIAL	Very limited regulatory infrastructure. CE Mark and FDA approvals serve as supporting documentation. CARICOM context; no formal reliance framework.	UNKNOWN
Japan	PMDA	PARTIAL	PMDA provides very limited reliance. Japan requires independent Japanese review for most classes. Some expedited pathways exist for urgent/innovative devices and certain Class II with CE Mark or FDA clearance, but a full PMDA review remains mandatory.	YES
Jordan	JFDA	YES	JFDA has a formal abbreviated registration pathway for devices approved by reference agencies (FDA, CE Mark, TGA, HSA, Health Canada). Prior reference approval significantly expedites and simplifies Jordanian registration.	YES
Kazakhstan	NCA RK / EAEU	PARTIAL	EAEU member. Devices registered under the EAEU unified procedure (primarily via Russia) are recognized across Kazakhstan. National expedited review also available for reference-approved devices.	YES
Kenya	PPB / KEBS	PARTIAL	PPB requires device registration. CE Mark, FDA, and WHO PQ approvals are required supporting documentation. EAC harmonization context; expedited review possible for reference-approved devices.	YES
Kosovo	AKPS	YES	EU accession candidate with EU-aligned regulations. CE Mark-certified devices recognized by AKPS — de facto reliance pathway consistent with EU MDR/IVDR.	YES
Kuwait	MOH Kuwait	YES	Kuwait MOH accepts devices approved by reference agencies (FDA, CE Mark, TGA, SFDA) under the GCC harmonization framework. SFDA approval is particularly influential.	YES
Kyrgyzstan	DSSA / EAEU	PARTIAL	EAEU member. Devices can be registered via the EAEU unified procedure; Russian/EAEU registration recognized across Kyrgyzstan.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Laos	DDFM	PARTIAL	DDFM has a nascent regulatory system. Foreign approvals (FDA, CE Mark) required as supporting documentation. ASEAN AMDD principles apply; formal reliance is limited.	YES
Latvia	ZVA	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. ZVA oversees market surveillance.	NO
Lebanon	MOH Lebanon	PARTIAL	MOH requires device registration. CE Mark and FDA approvals are mandatory supporting documentation and significantly influence review, but a local process must still be completed.	YES
Liechtenstein	AMS	YES	EEA member with bilateral agreement with Switzerland. EU MDR/IVDR applies via EEA Agreement and Swiss MRA. CE Mark grants full market access without additional national registration.	NO
Lithuania	VVKT	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. VVKT (State Medicines Control Agency) oversees market surveillance.	NO
Luxembourg	DMSPS	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. No separate Luxembourg national registration required.	NO
Malaysia	MDA	YES	MDA has an abbreviated registration pathway for devices approved by reference agencies (FDA, CE Mark, TGA, HSA, Health Canada). Prior reference approval significantly reduces documentation and review timelines.	YES
Maldives	MOH Maldives	PARTIAL	Very limited regulatory infrastructure. CE Mark and FDA approvals serve as required supporting documentation. No formal reliance framework codified.	UNKNOWN
Malta	Malta Medicines Authority	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. Malta Medicines Authority oversees market surveillance.	NO
Mauritius	MOH Mauritius	PARTIAL	MOH requires device import authorization. CE Mark and FDA approvals are mandatory supporting documentation. Relatively streamlined compared to other Sub-Saharan African markets.	YES
Mexico	COFEPRIS	YES	COFEPRIS has an abbreviated registration pathway for devices approved by reference agencies (FDA, CE Mark, Health Canada, TGA). Prior approval triggers expedited review with reduced documentation.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Moldova	ANMDM	PARTIAL	Under the EU-Moldova Association Agreement, CE Mark is increasingly recognized. ANMDM is developing a formal reliance framework aligned with EU MDR; codification is still in progress.	YES
Mongolia	MOH Mongolia	PARTIAL	MOH requires device registration. CE Mark and FDA approvals required as supporting documentation. No formal abbreviated pathway; limited regulatory capacity.	YES
Montenegro	CALIMS	YES	EU accession candidate. Medical device regulations aligned with EU MDR/IVDR. CE Mark recognized by CALIMS — de facto reliance pathway.	YES
Morocco	DPM / MAPEDPH	PARTIAL	MOH requires device registration. CE Mark is essentially a prerequisite; FDA approval may expedite review. A separate Moroccan registration process must be completed.	YES
Myanmar	FDA Myanmar	PARTIAL	FDA Myanmar requires device registration. CE Mark, FDA, and TGA approvals are required supporting documentation. ASEAN AMDD principles apply; formal reliance is limited.	YES
Namibia	NMRC	PARTIAL	NMRC gives weight to reference agency approvals (CE Mark, FDA, TGA, SAHPRA). SADC context. Reference approvals significantly support registration but no full abbreviated pathway.	YES
Netherlands	RIVM / CIBG	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. Netherlands hosts several major EU Notified Bodies.	NO
New Zealand	Medsafe	YES	Medsafe has a streamlined pathway for devices approved by reference agencies (TGA, FDA, CE Mark, Health Canada). Trans-Tasman Mutual Recognition Arrangement (TTMRA) means Australian TGA approval is particularly influential.	PARTIAL
Nicaragua	MINSa Nicaragua	PARTIAL	MINSa has limited regulatory capacity. Foreign approvals (FDA, CE Mark) serve as supporting documentation. COMISCA context; formal reliance limited.	YES
Nigeria	NAFDAC	PARTIAL	NAFDAC requires device registration. CE Mark and WHO PQ are required supporting documentation. ECOWAS harmonization context; reference approvals effectively mandatory.	YES
North Macedonia	MALMED	YES	EU accession candidate. Medical device regulations harmonized with EU MDR/IVDR. CE Mark recognized by MALMED — de facto reliance pathway.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Norway	NoMA	YES	EEA member state. EU MDR/IVDR applies via EEA Agreement. CE Mark grants full market access in Norway without additional national registration.	NO
Oman	MOH Oman	YES	Oman MOH accepts devices approved by reference agencies (FDA, CE Mark, TGA, SFDA) under the GCC harmonization framework. SFDA and CE Mark approvals are particularly influential.	YES
Pakistan	DRAP	PARTIAL	DRAP requires CE Mark or FDA approval as a mandatory prerequisite. A full local registration process is still required; no formal abbreviated reliance pathway.	YES
Palestine	MOH Palestine	PARTIAL	Very limited regulatory infrastructure. CE Mark and FDA approvals serve as required supporting documentation. No formal reliance framework; regulatory capacity is severely constrained.	UNKNOWN
Panama	MINSa / DNFD	PARTIAL	Reference country approvals (FDA, CE Mark) required as supporting documentation. Limited formal reliance; local registration process required.	YES
Paraguay	DINAVISa	PARTIAL	CE Mark and FDA approvals required as supporting documentation. No formal abbreviated reliance pathway; limited regulatory capacity.	YES
Peru	DIGEMID	YES	DIGEMID has an abbreviated registration pathway for devices approved by reference agencies (FDA, CE Mark, TGA, Health Canada, ANVISA). Prior reference approval enables simplified technical review.	YES
Philippines	FDA Philippines	YES	FDA Philippines has an abbreviated registration pathway for Class B/C/D devices approved by reference agencies (FDA, CE Mark, TGA, HSA, Health Canada). ASEAN AMDD implementation supports reliance principles.	YES
Poland	URPL	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. URPL oversees market surveillance.	NO
Portugal	INFARMED	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. INFARMED oversees market surveillance.	NO
Puerto Rico	FDA (US Territory)	YES	Puerto Rico is a US territory under FDA jurisdiction. All FDA regulations (510(k), PMA, De Novo) apply directly. FDA clearance/approval provides full market access — same as the US mainland.	NO



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Qatar	MOPH Qatar	YES	Qatar MOPH streamlined pathway for devices approved by reference agencies (FDA, CE Mark, TGA, SFDA). GCC harmonization facilitates mutual recognition.	YES
Republic of Serbia	ALIMS	YES	EU accession candidate. Serbian regulatory framework aligned with EU MDR/IVDR. CE Mark recognized by ALIMS — de facto reliance pathway for CE-certified devices.	YES
Romania	ANMDMR	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. ANMDMR oversees market surveillance.	NO
Russia	Roszdraznadzor	PARTIAL	Russia participates in EAEU unified registration (TR EAEU 017/2011). Some weight given to CE Mark and WHO-listed devices, but an independent Russian registration is always required.	YES
Rwanda	Rwanda FDA	PARTIAL	Rwanda FDA is undergoing modernization. CE Mark, FDA, and WHO PQ approvals required as supporting documentation. EAC harmonization context.	YES
Saudi Arabia	SFDA	YES	SFDA has a formal abbreviated registration pathway for devices approved by recognized reference agencies (FDA, CE Mark, TGA, Health Canada, MFDS, HSA). SFDA is itself recognized as a reference agency. GCC harmonization enables regional mutual recognition.	YES
Senegal	MSAS	PARTIAL	MOH requires import authorization. CE Mark and FDA approvals required as supporting documentation. ECOWAS harmonization context; no formal abbreviated pathway.	YES
Singapore	HSA	YES	HSA has one of Asia's strongest reliance frameworks. Devices approved by FDA, CE Mark, TGA, Health Canada, PMDA, MFDS receive abbreviated review. HSA is the ASEAN benchmark reference agency and is globally recognized.	YES
Slovakia	SUKL Slovakia	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. SUKL Slovakia oversees market surveillance.	NO
Slovenia	JAZMP	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. JAZMP oversees market surveillance.	NO
South Africa	SAHPRA	YES	SAHPRA has an expedited review pathway giving significant weight to SRA-listed agency approvals (FDA, CE Mark, TGA, Health Canada, EMA). SRA-listed manufacturers receive significantly reduced documentation requirements.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
South Korea	MFDS	YES	MFDS has an abbreviated review pathway for Class II/III devices approved by FDA or CE Mark. Prior reference approval reduces MFDS technical review requirements. MFDS is itself a recognized reference agency.	YES
Spain	AEMPS	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. AEMPS oversees market surveillance.	NO
Sri Lanka	NMRA	PARTIAL	NMRA requires device registration. CE Mark and FDA approvals are mandatory supporting documentation. A formal reliance pathway is being developed but not yet fully codified.	YES
Sudan	NMPB / SFDA Sudan	PARTIAL	Limited regulatory capacity. CE Mark and WHO PQ approvals required as supporting documentation. Conflict-affected governance significantly limits regulatory function.	YES
Suriname	MOH Suriname	PARTIAL	Very limited regulatory infrastructure. CE Mark and FDA approvals serve as supporting documentation. CARICOM context; no formal reliance framework.	UNKNOWN
Sweden	MPA	YES	EU member state (EU MDR/IVDR). CE Mark grants market access across all EU states. Medical Products Agency (MPA) oversees market surveillance.	NO
Switzerland	Swissmedic	YES	Switzerland has a Mutual Recognition Agreement (MRA) with the EU. CE Mark is fully recognized by Swissmedic, granting Swiss market access equivalent to EU MDR/IVDR.	NO
Syria	MOH Syria	UNKNOWN	Regulatory system severely impaired by ongoing conflict. No formal reliance pathway documented. Market access largely unregulated in many regions.	UNKNOWN
Taiwan	TFDA / MDCA	YES	TFDA (now MDCA) has a formal abbreviated registration pathway for Class II/III devices approved by FDA or CE Mark. Prior reference approval triggers expedited review under Taiwan's registration system.	YES
Tanzania	TMDA	PARTIAL	TMDA requires device registration. CE Mark, FDA, and WHO PQ approvals required as supporting documentation. EAC harmonization context; expedited review possible for reference-approved devices.	YES
Thailand	Thai FDA	YES	Thai FDA has an abbreviated registration pathway for Class III devices approved by FDA or CE Mark. Prior reference approval enables a shorter review track. ASEAN AMDD implementation supports reliance.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Tunisia	DPCM	PARTIAL	MOH requires device registration. CE Mark is essentially a prerequisite; a separate Tunisian registration process must still be completed.	YES
Turkey	TITCK	PARTIAL	TITCK requires CE Mark as a prerequisite for higher-risk device classes and has EU-aligned regulations. However, a separate Turkish registration must also be completed — significantly expedited for CE-marked devices.	YES
Turkmenistan	MOH Turkmenistan	PARTIAL	Very limited regulatory capacity. CIS framework partially applies. CE Mark and FDA approvals may be required as supporting documentation. No formal reliance pathway codified.	YES
Uganda	NDA Uganda	PARTIAL	NDA requires device registration. CE Mark, FDA, and WHO PQ approvals are required supporting documentation. EAC harmonization context; reference approvals effectively required.	YES
Ukraine	SMIDA	YES	Under the EU-Ukraine Association Agreement, CE Mark is recognized as the primary pathway. SMIDA accepts CE Mark-certified devices via a notification procedure — significant reliance mechanism aligned with EU MDR/IVDR.	YES
United Arab Emirates	MOHAP	YES	MOHAP has a formal abbreviated registration pathway for devices approved by reference agencies (FDA, CE Mark, TGA, SFDA, Health Canada). GCC harmonization facilitates regional mutual recognition.	YES
United Kingdom	MHRA	YES	Post-Brexit, MHRA has a formal Recognition Route for devices approved by FDA, TGA, Health Canada, and MDR CE Mark. CE Mark is recognized until June 2028. One of the strongest non-EU reliance frameworks globally.	PARTIAL
United States of America	FDA	NO	FDA is the primary global reference agency for medical devices. FDA does not rely on foreign regulatory approvals; all devices require FDA-specific submissions (510(k), PMA, De Novo). FDA is the reference — not a user of reliance.	NO
Uruguay	MSP	YES	Uruguay MSP has a simplified registration pathway for devices approved by reference agencies (FDA, CE Mark, TGA, ANVISA, ANMAT). Reference approval significantly reduces the technical review burden.	YES
Venezuela	INHRR	PARTIAL	INHRR requires device registration. CE Mark and FDA approvals required as supporting documentation. Economic and governance constraints limit regulatory function.	YES
Vietnam	DAV (MOH)	YES	Vietnam's Drug Administration (DAV) has an expedited registration pathway for Class C/D devices approved by reference agencies (FDA, CE Mark, TGA, Health Canada, HSA, MFDS). ASEAN AMDD context.	YES



Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Yemen	MOH Yemen	UNKNOWN	Regulatory system severely impaired by ongoing conflict. No formal reliance pathway documented. Market access is largely unregulated.	UNKNOWN
Zimbabwe	MCAZ	PARTIAL	MCAZ requires device registration. CE Mark, FDA, and WHO PQ approvals required as supporting documentation. SADC context; expedited review possible for WHO PQ or SRA-approved devices.	YES



Section 2 — Regional Bodies & Harmonization Frameworks

These entries represent regional regulatory bodies, economic communities, and international frameworks that operate across multiple countries.

Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
ASEAN (Regional)	ASEAN AMDD	PARTIAL	The ASEAN Medical Device Directive (AMDD) provides a harmonized regulatory framework and common submission dossier (CSDT). Promotes reliance principles; Singapore HSA is the ASEAN benchmark reference agency. Implementation varies by member state.	YES
Africa (Regional)	AUDA-NEPAD / AMA	PARTIAL	AUDA-NEPAD's African Medicines Regulatory Harmonization (AMRH) program promotes reliance across sub-regional communities (ECOWAS, EAC, SADC). The African Medicines Agency (AMA), established 2021, aims to build continent-wide reliance mechanisms.	PARTIAL
Americas (Regional)	PAHO / PANDRH	PARTIAL	PAHO's PANDRH promotes reliance among Latin American and Caribbean countries. No binding regional reliance framework exists for devices; strongest individual frameworks in Brazil, Colombia, Argentina, Chile, Peru.	PARTIAL
Asia-Pacific (Regional)	APEC RHSC / AHWP	PARTIAL	APEC's Regulatory Harmonization Steering Committee (RHSC) and the Asian Harmonization Working Party (AHWP) promote medical device regulatory convergence. Frameworks are advisory; ASEAN AMDD is the strongest sub-regional mechanism.	PARTIAL
Caribbean (Regional)	CARICOM / CARPHA	PARTIAL	CARPHA is developing harmonized regulatory standards for medical devices among CARICOM member states. Implementation is nascent; individual country regulatory capacity is very limited.	PARTIAL
East Africa (Regional)	EAC MRH	PARTIAL	The East African Community (EAC) Medicines Regulatory Harmonization (MRH) program promotes joint reviews and reliance mechanisms for medical devices among member states (Kenya, Tanzania, Uganda, Rwanda, Burundi, South Sudan).	PARTIAL
Europe (Regional)	EC / EMA	YES	EU MDR (2017/745) and IVDR (2017/746) provide the most advanced regional reliance framework globally. CE Mark grants market access across 27 EU member states plus EEA (Norway, Iceland, Liechtenstein) and Switzerland via MRA.	NO
European Union	EC / EMA / MDCG	YES	EU MDR/IVDR establishes a unified conformity assessment system. CE Mark grants market access across all 27 EU member states. The EU MDR/IVDR is the global benchmark for regional regulatory harmonization.	NO
Global	IMDRF / WHO	PARTIAL	IMDRF promotes global regulatory convergence and published reliance guidance (N67). WHO's Collaborative Procedure for Medical Devices provides a global reliance mechanism. Neither IMDRF nor WHO has binding authority over national regulators.	PARTIAL
Gulf Region (Regional)	GCC / SFDA	YES	The GCC harmonized medical device regulatory framework enables mutual recognition among member states (Saudi Arabia, UAE, Bahrain, Kuwait, Qatar, Oman). SFDA serves as the primary reference agency for the GCC region.	YES
International	IMDRF / ISO / IEC	PARTIAL	International frameworks (IMDRF N67, ISO 13485, IEC standards) provide the technical basis for regulatory reliance globally. IMDRF N67 guidance on reliance is widely referenced. These frameworks are advisory and non-binding.	PARTIAL
Middle East (Regional)	Various	PARTIAL	No unified Middle East regulatory framework exists. GCC countries have strong harmonization; Levant countries (Jordan, Lebanon, Israel) operate independently; conflict-affected states have minimal capacity.	PARTIAL



Section 3 — Special Chapter: No / Unknown Reliance Reporting

⚠ Countries with No or Unknown Reliance Pathway

The following **6 countries** either have **no formal reliance pathway** (NO) or their regulatory status is **undetermined / non-functional** (UNKNOWN). These markets typically require either full independent local registration, have severely constrained regulatory infrastructure, or represent reference agencies that are the source of reliance for others (e.g., the USA/FDA).

What this means for manufacturers: For countries marked NO, a complete standalone registration with the national authority is required — foreign approvals are not accepted as a basis for abbreviated review. For countries marked UNKNOWN, regulatory engagement is advised via an in-country regulatory consultant before proceeding.

Country / Territory	Regulatory Authority	Q1: Reliance Exists?	Q2: Pathway Description	Q3: FSC Required?
Afghanistan	NRAA	UNKNOWN	Regulatory system largely non-functional. Under current governance, no formal reliance pathway is documented. Market access is largely informal.	UNKNOWN
China	NMPA	NO	NMPA does not rely on foreign agency approvals. An independent Chinese registration is mandatory for all device classes, typically requiring Chinese clinical data, independent testing, and full technical review.	NO
Cuba	CECMED	NO	CECMED conducts independent regulatory review. No formal reliance pathway on foreign approvals. Geopolitical constraints further restrict access to reference-agency approvals.	UNKNOWN
Syria	MOH Syria	UNKNOWN	Regulatory system severely impaired by ongoing conflict. No formal reliance pathway documented. Market access largely unregulated in many regions.	UNKNOWN
United States of America	FDA	NO	FDA is the primary global reference agency for medical devices. FDA does not rely on foreign regulatory approvals; all devices require FDA-specific submissions (510(k), PMA, De Novo). FDA is the reference — not a user of reliance.	NO
Yemen	MOH Yemen	UNKNOWN	Regulatory system severely impaired by ongoing conflict. No formal reliance pathway documented. Market access is largely unregulated.	UNKNOWN