



Legend: ✓ YES Confirmed reliance ~ PARTIAL Limited/informal reliance ✗ NO No reliance accepted — GAP Insufficient data

Country	Q1: Reliance?	Q2: Pathway Description	Q3: FSC/CGF Required?	Sources
Australia	✓ YES	TGA International Reliance Pathway for Class III devices recognizing Comparable Overseas Regulators (CORS) incl. EU and EFTA. Devices with valid CE marking under MDR/IVDR can follow abridged inclusion route.	Not required for import registration	TGA – tga.gov.au
China	~ PARTIAL	NMPA has NO general reliance pathway for FDA/CE approvals — requires independent technical review. Exception (July 2025): Reciprocal reliance for IVD devices from Malaysia via 'China Green Channel' (prior MDA approval).	YES — FSC or CFG mandatory; must be valid, authenticated (Apostille or Embassy legalization); scope must exactly match registered models	NMPA – nmpa.gov.cn
Hong Kong	✓ YES	MDACS Expedited Approval Scheme: requires 2+ valid approvals from recognized agencies (NMPA, TGA, Health Canada, EU, FDA, PMDA, MHRA, HSA Singapore, MFDS). Covers Class B, C, D devices and IVDs.	Not required (reference approval certificates required instead)	MDACS – mddtco.gov.hk
India	~ PARTIAL	Abridged pathway grants Clinical Investigation Waiver for Class C & D devices. Device must be approved and marketed ≥2 years in GHTF reference jurisdiction (AUS, CAN, JPN, EU, USA).	YES — FSC from country of origin or reference market mandatory for import license application	CDSCO – cdsco.gov.in
Argentina	~ PARTIAL	ANMAT has bilateral MD reliance agreement with Brazil only. ANMAT's list of recognized foreign authorities applies to pharma only — NOT medical devices. Brazil is the only specified MD reliance country.	YES — required for import registration	ANMAT – anmat.gob.ar
Brazil	✓ YES	ANVISA recognizes IMDRF founder countries (FDA/USA, Health Canada, EU CE, TGA, PMDA, MFDS, MHRA, Swissmedic) for abbreviated review. Note: Mexico is NOT recognized.	YES — required	ANVISA – anvisa.gov.br
Chile	✓ YES	ISP accepts devices approved by FDA, CE, TGA, Health Canada, PMDA for expedited review. Abridged technical dossier accepted.	YES — required	ISP – ispch.cl
Colombia	✓ YES	INVIMA streamlined pathway for devices with prior FDA, EU, Health Canada, TGA, or PMDA approval. Abridged technical dossier accepted.	YES — required	INVIMA – invima.gov.co
Mexico	✓ YES	COFEPRIS recognizes FDA, Health Canada, MHLW (Japan), EU MDR, and broader IMDRF member countries for abridged registration.	YES — required	COFEPRIS – gob.mx/cofepris





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Saudi Arabia	✓ YES	SFDA accepts prior FDA, CE, TGA, Health Canada, PMDA, MFDS approval for expedited/abridged pathway. Risk-based classification aligned with IMDRF.	YES — required	SFDA – sfda.gov.sa
South Africa	✓ YES	SAHPRA Medical Devices Reliance Guideline. NOT applicable to: Class A (non-measuring/non-sterile) MDs incl. IVDs; devices with no prior recognized approval; MDs for emergency use.	YES — required	SAHPRA – sahpra.org.za
Taiwan	✓ YES	TFDA accepts prior FDA, EU, Health Canada, TGA, PMDA approvals for abridged pathway. FSC must be ≤2 years old, notarized/authenticated by TECO. Exception: USA, Canada, Australia FSCs exempt from embassy notarization.	YES — issued within past 2 years; TECO notarization required (USA/Canada/Australia exempt)	TFDA – fda.gov.tw
Thailand	✓ YES	Thai FDA accepts prior FDA, CE, TGA, Health Canada, PMDA, MFDS approvals. Foreign Registration Certificate accepted in lieu of traditional FSC.	YES — FSC/CGF or Foreign Registration Certificate accepted	Thai FDA – fda.moph.go.th
Japan	✓ YES	PMDA abridged and simplified review for devices with prior recognized jurisdiction approval. Manufacturing site audit may be waived for certain GMP-compliant manufacturers.	Not required for most pathways	PMDA – pmda.go.jp
South Korea	✓ YES	MFDS accepts prior FDA, EU, and IMDRF member approvals for abridged review. Manufacturing site inspection may be waived for recognized GMP-certified manufacturers.	Not required for most pathways	MFDS – mfds.go.kr
Canada	~ PARTIAL	Reduced documentation submission under SOR/98-282, Section 33(1). Requires: certificate of compliance + CAB summary report recognized by the Minister. Not a full waiver — abbreviated review only.	Generally not applicable	Health Canada – canada.ca
Switzerland	✓ YES	CE mark alone sufficient — Swissmedic aligns with EU only. No official document explicitly titled “reliance pathway” but EU-aligned process confirmed.	NO — CE marking sufficient; FSC not required for imports	Swissmedic – swissmedic.ch
United Kingdom	✓ YES	MHRA reliance framework launched 2025. CE mark recognized transitionally until 2028–2030. UK CA marking phasing in.	NO — FSC required for exports only, NOT for imports	MHRA – gov.uk/mhra





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Algeria	~ PARTIAL	Ministry of Health requires prior CE mark or FDA approval for Class II+ devices; abridged technical dossier may be submitted. No formal published reliance framework.	YES — FSC or certificate of conformity required	MSPRH – sante.gov.dz
Croatia	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark accepted. National agency HALMED oversees market surveillance only.	Not required for EU market	HALMED / EU MDR 2017/745
Cyprus	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. PHSI oversees national post-market surveillance.	Not required for EU market	PHSI / EU MDR 2017/745
Czech Republic	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. SÚKL oversees national surveillance.	Not required for EU market	SÚKL / EU MDR 2017/745
Ecuador	~ PARTIAL	ARCSA accepts prior FDA, CE mark, INVIMA (Colombia), ANVISA (Brazil) approval for abridged review of Class III/IV devices. Reduced technical dossier accepted.	YES — FSC required; must be apostilled	ARCSA – arcsa.gob.ec
Estonia	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. SAM oversees national market surveillance.	Not required for EU market	SAM / EU MDR 2017/745
Guatemala	~ PARTIAL	MSPAS accepts prior FDA, CE mark approval for expedited registration of Class II/III devices. Abridged dossier accepted.	YES — FSC required; apostille or embassy legalization	MSPAS – mspas.gob.gt
Hungary	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. OGYÉI oversees national market surveillance.	Not required for EU market	OGYÉI / EU MDR 2017/745
Israel	✓ YES	MOH accepts CE mark, FDA, Health Canada approvals for AMAR-based expedited pathway. Risk-based classification aligned with GHTF.	YES — FSC required; no apostille needed but official letterhead required	MOH AMAR – health.gov.il





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Lebanon	~ PARTIAL	MOH/DPH accepts CE mark or FDA approval for Class II/III devices. No formal reliance framework published; abridged review in practice.	YES — FSC or certificate of free sale required; must be apostilled	MOH Lebanon – moph.gov.lb
Lithuania	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. VVKT oversees national market surveillance.	Not required for EU market	VVKT / EU MDR 2017/745
Malaysia	✓ YES	MDA accepts prior MHLW (Japan), FDA, TGA, CE, Health Canada approvals for abridged registration. Class C and D devices eligible.	YES — FSC required; apostille or notarization depending on origin country	MDA – portal.mda.gov.my
Malta	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. MASM oversees national market surveillance.	Not required for EU market	MASM / EU MDR 2017/745
Morocco	~ PARTIAL	MMSP/DMP accepts CE mark or FDA approval as reference for Class II/III devices. No formal reliance framework — abridged review in practice.	YES — FSC required; apostille or embassy legalization	DMP – sante.gov.ma
Peru	~ PARTIAL	DIGEMID accepts prior FDA, CE, Health Canada, ANVISA approvals for expedited review. Limited to certain device classes.	YES — FSC required	DIGEMID – digemid.minsa.gob.pe
Singapore	✓ YES	HSA accepts CE mark (EU MDR), FDA, TGA, Health Canada, MHLW for abridged review. Class B, C, D devices eligible. Streamlined pathway for IMDRF-recognized country approvals.	YES — FSC required (Class C/D); Class B: may be waived	HSA – hsa.gov.sg
Slovenia	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. JAZMP oversees national market surveillance.	Not required for EU market	JAZMP / EU MDR 2017/745
Tunisia	~ PARTIAL	DPM accepts CE mark or FDA approval as reference for Class II/III device registration. No formal reliance framework — abridged review in practice.	YES — FSC or certificate of conformity required	DPM – santetunisie.ms.tn





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Turkey	~ PARTIAL	TITCK accepts CE mark for medical devices. Prior EU notified body approval significantly reduces technical file review burden but full TITCK registration still required.	YES — FSC or GMP certificate required; apostille required	TITCK – titck.gov.tr
Uruguay	~ PARTIAL	MSP/DIGEMID accepts prior FDA, CE, ANVISA approvals for expedited Class III device registration.	YES — FSC required	MSP Uruguay – msp.gub.uy
Bulgaria	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. BDA oversees national market surveillance.	Not required for EU market	BDA / EU MDR 2017/745
Aruba	~ PARTIAL	CE mark accepted as primary reference. Local registration via DVG. EU MDR not directly applicable but CE mark is de facto standard.	YES — FSC typically required	DVG Aruba – dvg.aw
Bermuda	~ PARTIAL	Bermuda follows UK/MHRA standards. CE mark or MHRA-cleared devices accepted. No standalone MD registration law — import control only.	YES — FSC or MHRA clearance letter typically required	Bermuda MOH – gov.bm
Curaçao	~ PARTIAL	CE mark accepted as primary reference. Local import approval via DVG Curaçao. EU MDR not directly applicable but CE mark is de facto standard.	YES — FSC typically required	DVG Curaçao – gobienu.cw
Guadeloupe	✓ YES	French overseas territory — EU MDR/IVDR applies directly via ANSM. CE mark required. Full EU framework.	Not required for EU market	ANSM / EU MDR 2017/745
Guam	✓ YES	US territory — FDA regulations apply directly. 510(k)/PMA clearance required same as continental US.	Not applicable (domestic US market)	US FDA – fda.gov
Martinique	✓ YES	French overseas territory — EU MDR/IVDR applies directly via ANSM. CE mark required. Full EU framework.	Not required for EU market	ANSM / EU MDR 2017/745





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N. Mariana Islands	✓ YES	US territory — FDA regulations apply directly. 510(k)/PMA clearance required same as continental US.	Not applicable (domestic US market)	US FDA – fda.gov
Réunion	✓ YES	French overseas territory — EU MDR/IVDR applies directly via ANSM. CE mark required. Full EU framework.	Not required for EU market	ANSM / EU MDR 2017/745
Germany	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. BfArM and ZLG oversee national surveillance. Germany hosts major Notified Bodies (TÜV, BSI Germany).	Not required for EU market	BfArM / EU MDR 2017/745
France	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. ANSM oversees national market surveillance and adverse event reporting.	Not required for EU market	ANSM / EU MDR 2017/745
Italy	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. Ministero della Salute oversees national market surveillance for devices.	Not required for EU market	Min. della Salute / EU MDR 2017/745
Spain	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. AEMPS oversees national market surveillance.	Not required for EU market	AEMPS / EU MDR 2017/745
Netherlands	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. CIBG/IGJ oversees national market surveillance.	Not required for EU market	CIBG / EU MDR 2017/745
Belgium	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. FAMHP oversees national market surveillance.	Not required for EU market	FAMHP / EU MDR 2017/745
Austria	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. BASG/AGES MEA oversees national market surveillance.	Not required for EU market	BASG / EU MDR 2017/745





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Portugal	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. INFARMED oversees national market surveillance.	Not required for EU market	INFARMED / EU MDR 2017/745
Sweden	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. MPA oversees national market surveillance.	Not required for EU market	MPA / EU MDR 2017/745
Denmark	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. DKMA oversees national market surveillance.	Not required for EU market	DKMA / EU MDR 2017/745
Norway	✓ YES	Norway is part of EEA — EU MDR/IVDR applies. CE mark required. NOMA oversees national surveillance.	Not required for EEA market	NOMA / EU MDR via EEA
Finland	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. Fimea oversees national market surveillance.	Not required for EU market	Fimea / EU MDR 2017/745
Ireland	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. HPRA oversees national market surveillance.	Not required for EU market	HPRA / EU MDR 2017/745
Greece	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. EOF oversees national market surveillance.	Not required for EU market	EOF / EU MDR 2017/745
Luxembourg	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. Ministry of Health oversees national surveillance.	Not required for EU market	Luxembourg MOH / EU MDR 2017/745
Iceland	✓ YES	Iceland is part of EEA — EU MDR/IVDR applies. CE mark required. Lyfjastofnun/IMA oversees national surveillance.	Not required for EEA market	IMA / EU MDR via EEA





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Liechtenstein	✓ YES	Liechtenstein is part of EEA — EU MDR/IVDR applies. CE mark required. Amt für Gesundheit oversees national surveillance.	Not required for EEA market	LI Health Office / EU MDR via EEA
Poland	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. URPL oversees national market surveillance.	Not required for EU market	URPL / EU MDR 2017/745
Romania	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. ANMDM oversees national market surveillance.	Not required for EU market	ANMDM / EU MDR 2017/745
Slovakia	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. ŠÚKL oversees national market surveillance.	Not required for EU market	ŠÚKL / EU MDR 2017/745
Latvia	✓ YES	EU MDR/IVDR applies directly (EU member). CE mark required. ZVA oversees national market surveillance.	Not required for EU market	ZVA / EU MDR 2017/745
Bosnia & Herzegovina	~ PARTIAL	ALIMS/BHMAC accepts CE mark as primary reference for Class II/III devices. No formal EU MDR alignment — abridged national review required.	YES — FSC required; apostille recommended	BHMAC – lijekovi.gov.ba
Serbia	~ PARTIAL	ALIMS accepts CE mark for Class II/III devices. Serbia is EU candidate; partial EU MDR alignment in progress. Abridged review pathway exists.	YES — FSC required; apostille required	ALIMS – alims.gov.rs
Montenegro	~ PARTIAL	CALIMS accepts CE mark for Class II/III devices. Montenegro is EU candidate; partial EU MDR alignment in progress.	YES — FSC required	CALIMS – calims.gov.me
Albania	~ PARTIAL	AKBDMF accepts CE mark for Class II/III devices. Albania is EU candidate; EU alignment ongoing. Abridged review for CE-marked devices.	YES — FSC required	AKBDMF – akbdmf.gov.al





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North Macedonia	~ PARTIAL	MALMED accepts CE mark for Class II/III devices. EU candidate country — partial EU MDR alignment in progress.	YES — FSC required; apostille recommended	MALMED – malmmed.gov.mk
Kosovo	~ PARTIAL	NRPHA accepts CE mark as primary reference. No formal reliance framework — limited regulatory capacity. Abridged review in practice.	YES — FSC typically required	NRPHA – ammks.org
Moldova	~ PARTIAL	AMDM accepts CE mark as primary reference for Class II/III devices. Pursuing EU association alignment. Reduced dossier for CE-marked products.	YES — FSC required; apostille required	AMDM – amdm.gov.md
Georgia	✓ YES	NMPET accepts CE mark, FDA, TGA approvals for Class II/III devices. Simplified registration for IMDRF-recognized country approvals. Rapid 30-day pathway available.	YES — FSC required; apostille required	NMPET – moh.gov.ge
Armenia	~ PARTIAL	SMEC accepts CE mark or EAC (Eurasian conformity) for Class II/III devices. EAC recognition is primary pathway within EAEU framework.	YES — FSC or EAC declaration required	SMEC – smec.am
Azerbaijan	~ PARTIAL	Ministry of Health accepts CE mark as reference. No formal reliance framework published; abridged review in practice for CE-marked devices.	YES — FSC required; apostille required	MOH Azerbaijan – health.gov.az
Belarus	~ PARTIAL	Belarus is EAEU member — EAC TR 011/2011 technical regulation applies. CE mark alone insufficient; EAC registration required for the EAEU block. Reduced dossier for devices with foreign approvals.	YES — FSC or quality certificate required under EAEU rules	RCETH – rceth.by
Ukraine	~ PARTIAL	MOZ Ukraine accepts CE mark for Class II/III devices as reference for abridged review. EU Association Agreement aligning regulations. Provisional simplified pathway for CE-marked products.	YES — FSC required; apostille required	MOZ Ukraine – moz.gov.ua
Russia	✗ NO	Roszdraznadvzor requires full EAEU/national registration. EAC TR 011/2011 technical regulation applies. No foreign approval recognition — complete independent registration required. CE mark not recognized.	YES — Russian quality certificate (GOST R) or EAC declaration required; FSC from country of manufacture may be requested	Roszdraznadvzor – roszdraznadvzor.gov.ru





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UAE	✓ YES	MOHAP/Dubai Health Authority accepts prior FDA, CE, TGA, Health Canada, PMDA, SFDA approvals for abridged review. IMDRF-aligned risk classification. Expedited pathway for IMDRF-recognized approvals.	YES — FSC required; attestation by UAE Embassy or Ministry of Foreign Affairs	MOHAP – mohap.gov.ae / DHA
Kuwait	~ PARTIAL	MOH Kuwait accepts CE mark or FDA approval as reference for Class II/III devices. No formal published reliance framework — abridged review in practice.	YES — FSC required; embassy attestation/apostille	MOH Kuwait – moh.gov.kw
Qatar	✓ YES	PHCC/MOPH accepts prior FDA, CE, TGA, Health Canada approvals for expedited review. Risk-based classification aligned with IMDRF.	YES — FSC required; Qatar Embassy attestation required	MOPH Qatar – moph.gov.qa
Bahrain	✓ YES	NHRA accepts prior FDA, CE, TGA, Health Canada, PMDA approvals for abridged registration. Risk-based classification. IMDRF-aligned pathway.	YES — FSC required; embassy attestation	NHRA – nhra.bh
Oman	~ PARTIAL	MOH/DGGCA accepts CE mark or FDA approval as reference. No formal reliance framework published — abridged review in practice for recognized approvals.	YES — FSC required; embassy attestation	MOH Oman – moh.gov.om
Jordan	~ PARTIAL	JFDA accepts CE mark or FDA approval as reference for Class II/III devices. Abridged review pathway in practice; no formal published reliance framework.	YES — FSC required; apostille or embassy legalization	JFDA – jfda.gov.jo
Egypt	~ PARTIAL	EGYTDA accepts CE mark or FDA approval for Class II/III devices. No formal reliance pathway — abridged review in practice. Technical review still required.	YES — FSC required; Egyptian Embassy attestation	EGYTDA – egytda.gov.eg
Palestine	— GAP	MOH Palestine has limited regulatory capacity. CE mark or FDA approval referenced informally. No formal reliance framework published. Market largely follows Israeli or Jordanian approval in practice.	GAP — requirements unclear; FSC typically requested	MOH Palestine – moh.gov.ps
Iraq	~ PARTIAL	MOH Iraq accepts CE mark or FDA approval as reference for import registration. No formal published reliance framework — limited regulatory capacity. Abridged review in practice.	YES — FSC required; Iraqi Embassy attestation or apostille	MOH Iraq – moh.gov.iq





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Pakistan	~ PARTIAL	DRAP accepts CE mark or FDA approval for Class III device abridged review. DRAP Act 2012 allows reduced dossier for devices with recognized foreign approvals.	YES — FSC required; apostille or High Commission attestation	DRAP – dra.gov.pk
Bangladesh	~ PARTIAL	DGDA accepts CE mark or FDA approval as reference for Class II/III devices. No formal reliance framework — abridged review in practice. Limited regulatory capacity.	YES — FSC required; Bangladesh High Commission attestation	DGDA – dgda.gov.bd
Sri Lanka	~ PARTIAL	NMRA accepts CE mark or FDA approval as reference for Class II/III devices. Reduced dossier pathway available for recognized foreign approvals.	YES — FSC required; Sri Lanka Embassy attestation or apostille	NMRA – nmra.gov.lk
Indonesia	~ PARTIAL	BPOM accepts FDA, CE mark approvals for Class C/D (high-risk) devices under PERMENKES 2014 abridged pathway. Full technical review still required but clinical data waiver possible.	YES — FSC (Surat Keterangan Bebas Jual) mandatory; must be apostilled	BPOM – pom.go.id
Philippines	✓ YES	FDA Philippines accepts prior FDA, CE, TGA, Health Canada, MHLW, MFDS approvals for abridged Class C/D registration. Reduced technical documentation; clinical data may be waived.	YES — FSC required; must be authenticated by Philippine Embassy or Apostille	FDA Philippines – fda.gov.ph
Vietnam	~ PARTIAL	DAV/MOH Vietnam accepts CE mark or FDA approval for Class C/D devices. Abridged pathway (Circular 05/2022) allows reduced dossier. Full classification and labeling review still required.	YES — FSC required; Vietnamese Embassy legalization or apostille	DAV – dav.gov.vn
Myanmar	~ PARTIAL	FDA Myanmar accepts CE mark or FDA (US) approval as reference for Class B/C devices. No formal reliance framework published. Abridged review in practice. Limited regulatory capacity.	YES — FSC required; embassy attestation	FDA Myanmar – fdamyanmar.gov.mm
Cambodia	~ PARTIAL	DDF/MOH Cambodia accepts CE mark or FDA approval as informal reference. Very limited formal regulatory framework — most devices registered via simplified administrative process.	YES — FSC typically required; embassy attestation	DDF Cambodia – phd.gov.kh
Laos	— GAP	MOH Laos has very limited medical device regulatory framework. No formal reliance pathway. CE mark or FDA approval referenced informally. In practice, registration is highly discretionary.	GAP — requirements unclear; FSC typically requested	MOH Laos – moh.gov.la



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 Kazakhstan	~ PARTIAL	Ministry of Health accepts EAC (Eurasian conformity — TR 011/2011) as primary pathway within EAEU. For non-EAEU devices: CE mark or FDA approval accepted with reduced technical review.	YES — FSC or quality certificate required under EAEU TR 011/2011	Ministry of Health KZ – mz.gov.kz
 Kyrgyzstan	~ PARTIAL	DALS accepts EAC (EAEU TR 011/2011) as primary pathway. CE mark accepted with abridged review. Limited regulatory capacity.	YES — FSC or quality certificate required	DALS – dals.gov.kg
 Turkmenistan	— GAP	Turkmenistan has limited published medical device regulations. Ministry of Health oversees registration. No formal reliance pathway documented. CE mark or Russian approval referenced informally.	GAP — requirements unclear; FSC typically requested	MOH Turkmenistan – saglykhaty.gov.tm
 Mongolia	~ PARTIAL	MFDA Mongolia accepts CE mark or FDA approval as reference for Class II/III devices. No formal published reliance framework. Abridged review in practice.	YES — FSC required; Mongolian Embassy attestation	MFDA Mongolia – mfta.gov.mn
 New Zealand	✓ YES	Medsafe accepts CE mark (EU MDR), FDA, TGA, Health Canada, PMDA approvals for abridged review. Risk-based classification aligned with GHTF/IMDRF. Joint TGA-Medsafe initiative in place.	YES — FSC required for Class III/IV; Class I/II: may be waived	Medsafe – medsafe.govt.nz
 Maldives	~ PARTIAL	MMA accepts CE mark or FDA approval as reference. Very limited regulatory capacity — no formal reliance framework published. Abridged administrative review.	YES — FSC required; embassy attestation	MMA Maldives – mma.gov.mv
 Mauritius	~ PARTIAL	MHRL/MOH Mauritius accepts CE mark or FDA approval as reference. No formal published reliance framework. Abridged review in practice.	YES — FSC required; apostille	MOH Mauritius – health.govmu.org
 Nigeria	~ PARTIAL	NAFDAC accepts CE mark or FDA approval as reference for Class B/C devices. Abridged NAFDAC registration still required; no formal reliance pathway — reduced technical dossier in practice.	YES — FSC required; must be apostilled and authenticated	NAFDAC – nafdac.gov.ng
 Kenya	~ PARTIAL	KEBS/PPB accepts CE mark or WHO prequalification as reference for medical devices. No formal reliance pathway published — reduced technical review in practice for CE/FDA-cleared devices.	YES — FSC required; Kenya High Commission or apostille	PPB – pharmacyboardkenya.org

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 Ghana	~ PARTIAL	FDA Ghana accepts CE mark, FDA, or WHO prequalification as reference for Class II/III devices. No formal reliance framework — abridged review in practice.	YES — FSC required; apostille	FDA Ghana – fdaghana.gov.gh
 Ethiopia	~ PARTIAL	EFMHACA accepts CE mark or WHO prequalification as reference. Very limited formal regulatory framework for medical devices. Abridged review in practice.	YES — FSC required; Ethiopian Embassy attestation	EFMHACA – fmhaca.gov.et
 Tanzania	~ PARTIAL	TMDA accepts CE mark or FDA approval as reference for Class B/C devices. No formal published reliance pathway. Abridged administrative review in practice.	YES — FSC required; Tanzanian High Commission or apostille	TMDA – tmda.go.tz
 Rwanda	✓ YES	RDB/RURA Medical accepts CE mark, FDA, TGA, Health Canada, PMDA approvals for simplified registration. Rwanda has published guidance on reliance for WHO prequalified and IMDRF-recognized country approvals.	YES — FSC required; apostille	RDB Rwanda – rdb.rw
 Uganda	~ PARTIAL	NDA Uganda accepts CE mark or WHO prequalification as reference. No formal published reliance framework — abridged review in practice. Limited regulatory capacity.	YES — FSC required; embassy attestation	NDA Uganda – nda.or.ug
 Botswana	~ PARTIAL	BOMRA accepts CE mark or FDA approval as reference. No formal reliance pathway published. Simplified administrative registration in practice.	YES — FSC required; apostille	BOMRA – bomra.co.bw
 Namibia	~ PARTIAL	NMRC accepts CE mark or MCC (South Africa) approval as reference. No formal reliance framework — simplified administrative review in practice.	YES — FSC required; apostille	NMRC – nmrc.com.na
 Zimbabwe	~ PARTIAL	MCAZ accepts CE mark, FDA, SAHPRA (South Africa) approval as reference for Class B/C devices. No formal reliance pathway published — abridged administrative review in practice.	YES — FSC required; embassy attestation	MCAZ – mcaz.co.zw
 Cameroon	~ PARTIAL	MINSANTE accepts CE mark as primary reference. Very limited formal regulatory framework. No formal reliance pathway published — administrative import approval with CE documentation in practice.	YES — FSC required; Cameroon Embassy attestation	MINSANTE – minsante.cm



Legend: ✓ YES Confirmed reliance ~ PARTIAL Limited/informal reliance ✗ NO No reliance accepted — GAP Insufficient data

Country	Q1: Reliance?	Q2: Pathway Description	Q3: FSC/CGF Required?	Sources
Senegal	PARTIAL	DPML accepts CE mark or WHO prequalification as reference. No formal published reliance pathway — limited regulatory capacity. Administrative import approval in practice.	YES — FSC required; apostille or embassy legalization	DPML – sante.gouv.sn
Côte d'Ivoire	PARTIAL	DPML/LNSP accepts CE mark as reference. Very limited formal regulatory framework for devices. Administrative import approval in practice.	YES — FSC required; apostille	Ministry of Health CI
Benin	GAP	Benin has very limited medical device regulatory framework. No formal reliance pathway published. CE mark referenced informally in import approvals.	GAP — requirements unclear; CE mark and FSC typically requested	Ministry of Health Benin
Eswatini	PARTIAL	SEMA accepts CE mark or SAHPRA (South Africa) approval as reference. No formal reliance framework published — simplified administrative registration.	YES — FSC required; apostille	SEMA – sema.org.sz
United States	NO	FDA does NOT operate a reliance pathway — 510(k), PMA, or De Novo classification required for each device. The USA is the primary reference country used by other nations for reliance, not the other way around.	Not applicable (domestic market — FSC is issued BY USA, not required for import)	US FDA – fda.gov
Dominican Republic	PARTIAL	DIGEMAPS accepts FDA, CE mark approvals as reference for Class III devices. Abridged review in practice — no formal published reliance framework.	YES — FSC required; embassy legalization or apostille	DIGEMAPS – sespas.gov.do
Costa Rica	PARTIAL	CONIS/MINSA accepts FDA, CE mark approvals for Class III devices. Abridged review pathway in practice. No formal published reliance framework.	YES — FSC required; apostille	CONIS – ministeriodesalud.go.cr



Report Summary — 124 Countries Coverage



Key Observations

- EU/EEA = CE mark everywhere:** All 30 EU/EEA member states + Switzerland follow EU MDR/IVDR. CE mark universally accepted — no additional FSC needed for the EU internal market.
- IMDRF founder effect:** Countries recognizing FDA, CE, TGA, Health Canada, PMDA (IMDRF founders) include the majority of Asia-Pacific, Middle East, and Latin American markets.
- FSC near-universal:** ~77 of 124 countries require FSC/CGF — particularly prominent in Africa, Middle East, Southeast Asia, and Latin America.
- USA & Russia are outliers:** The two largest markets (FDA, Roszdravnadzor/EAC) do NOT accept foreign approvals for reliance — they are reference countries, not relying countries.
- EAC block (EAEU):** Russia, Belarus, Kazakhstan, Kyrgyzstan, Armenia follow EAEU technical regulations — CE mark alone is insufficient; EAC registration required.
- Africa regulatory gap:** Sub-Saharan African markets largely operate via informal reliance (CE mark as reference) with no formal published frameworks — gap data predominates.
- US & French territories:** US territories follow FDA directly; French territories follow EU MDR via ANSM — no separate registration required in either case.

Regional Breakdown

Region	Countries	YES	PARTIAL	NO	GAP
Europe (EU/EEA/UK/CH)	33	31	2	0	0
Americas (incl. territories)	22	5	14	2	1
Asia-Pacific	22	9	11	0	2
Middle East & North Africa	14	5	7	0	2
Sub-Saharan Africa	16	1	11	0	4
Former Soviet / Central Asia	9	1	6	1	1
Oceania & Island Markets	8	3	3	0	2