

REGDESK REGULATORY INTELLIGENCE · JULY 2026

Global Medical Device Regulatory Pathways & Best Approach Guide

Covering 128+ Global Markets · All Device Classes (Class I, II, III & IVD)
Strategic Registration Intelligence for Medical Device Manufacturers · RegDesk Platform

118+

Global Markets Covered

6

Strategic Approach Types (A–F)

All Classes

Class I, II, III & IVD Covered

81

Reliance-Eligible Markets

31

Full Independent Registration Markets

Executive Summary

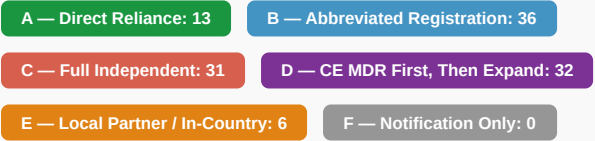
This report answers one critical question for each of 118 global medical device markets: **"What is the most efficient regulatory pathway to approval?"** Each country is assigned a Best Approach code (A–F) based on its reliance policy, regulatory maturity, typical timelines, and cost-effectiveness for manufacturers holding or pursuing CE MDR, FDA, or TGA certification.

Data covers all device classes (Class I, II, III, and IVD) with authority names, official agency URLs, classification systems, pathway names, realistic timelines, USD-equivalent fees, accepted reliance references, and a unique strategic note per market to guide market entry decisions.

💡 Strategic Insight: Start with CE MDR — The Global Reliance Anchor

CE MDR certification (EU Regulation 2017/745) is accepted as reliance or reference basis in **70+ markets** worldwide — more than any other single certification. Markets spanning the Middle East (SFDA Priority Review), Southeast Asia (HSA full reliance), Latin America (ANVISA abbreviated pathway), Africa (SAHPRA, NAFDAC), and non-EU Europe (Turkey, Switzerland, Balkans) all leverage CE MDR. A CE MDR + FDA dual-track strategy opens the broadest global access with the least duplication of effort. Obtain CE MDR first; then leverage it globally.

Approach Code Distribution Across 118 Markets



Best Approach Framework (A–F)

Approach Code & Name	Description & Typical Timeline	# Markets
A — Direct Reliance	Country fully accepts FDA 510(k)/PMA, CE MDR, or TGA as basis. Submit reference + local docs. Typical: 2–6 months.	13
B — Abbreviated Registration	Accelerated review based on CE/FDA/TGA but still requires local submission. Typical: 3–12 months.	36
C — Full Independent	No recognized reliance. Full technical dossier; local testing may be required. Typical: 12–36 months.	31
D — CE MDR First, Then Expand	CE MDR is the most efficient gateway for this market. Prioritize CE; then use for regional reliance.	32
E — Local Partner / In-Country	Requires local authorized representative, in-country testing/QMS audit, or significant local partnership.	6
F — Notification Only	Simple notification or listing; no pre-market approval required. Fastest pathway.	0

Global Reliance Intelligence — Which Certifications Open the Most Markets?

The table below shows how many of 118 analyzed markets accept each major international certification as a reliance basis or shortened review pathway. CE MDR dominates globally — securing CE MDR first maximizes market access efficiency.

Certification	Markets	Coverage %	Key Markets Accepting as Reliance / Reference
CE MDR / IVDR	113	96%	All 30 EU/EEA states, UK (until 2030), Turkey, Saudi Arabia, UAE, Qatar, Kuwait, Bahrain, Oman, Jordan, Singapore, Malaysia, Indonesia, Thailand, Vietnam, Philippines, Israel, South Korea, Taiwan, Aus
FDA 510(k) / PMA / De Novo	63	53%	Canada, Mexico, Colombia, Chile, Argentina, Singapore, Malaysia, South Korea, Taiwan, Hong Kong, Australia, New Zealand, Israel, Saudi Arabia, UAE, UK, Turkey, Brazil, India, Sri Lanka, Jamaica, Trini
TGA (Australia)	9	8%	New Zealand (full reliance), Singapore (full reliance), Malaysia (supporting), Papua New Guinea, Fiji, Brunei
WHO PQ (Prequalification)	5	4%	Bangladesh, Nepal, Ethiopia, Uganda, Tanzania, Laos, Cambodia — critical for LMIC public procurement
Health Canada	0	0%	Canada only (reference market); limited value as reliance in other markets
UKCA (Post-2030)	0	0%	UK only post-June 2030; CE MDR accepted until 2030 transition. UKCA has minimal reliance value outside UK currently

Recommended Certification Priority

1st:

CE MDR (EU) — highest global reliance coverage (70+ markets)

2nd:

FDA 510(k)/PMA — essential for Americas + East Asia

3rd:

TGA (Australia) — unlocks Pacific + some ASEAN markets

4th:

WHO PQ — critical for LMIC public procurement (IVD priority)

Dual-Track Strategy: CE MDR + FDA

CE MDR + FDA dual certification covers 100+ markets efficiently. Many Asian markets (S. Korea, Taiwan, Singapore, Malaysia) accept both. Latin America accepts both. GCC Gulf states accept both. This combination eliminates redundant full dossiers in 80%+ of addressable markets.


North America

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Canada	North America	Health Canada (MDEL)	canada.ca/health-canada	Class I–IV (CMDR SOR/98-282)	MDEL listing	Device Licence; abbreviated for FDA/CE holders	Class III–IV IVD: full review; Class I–II: MDEL only	15 days (II); 75 days (III); 300 days (IV)	CAD 500–5,700 (~USD 370–4,200)	FDA 510(k)/PMA; CE MDR (abbreviated pathway)	B	Leverage FDA or CE for abbreviated Class III/IV review. Mandatory bilingual labeling (EN/FR). Application via HPFB eSubmission Gateway.
Mexico	North America	COFEPRIS	gob.mx/cofepris	Class I–III (NOM-137-SSA1)	Aviso de Funcionamiento (notice)	Registro Sanitario; CE/FDA holders: abbreviated	Full sanitary registration; Class III IVD needs clinical data	3–6 mo (abbreviated); 12–18 mo (full)	MXN 10,000–80,000 (~USD 600–4,800)	FDA 510(k)/PMA; CE MDR (abbreviated review)	B	CE or FDA holders apply via abbreviated pathway. Appoint Mexican legal representative. COFEPRIS reform ongoing — timelines improving.
USA	North America	FDA / CDRH	fda.gov/medical-devices	Class I–III (21 CFR)	510(k) Exempt / Establishment Registration	510(k) Premarket Notification; PMA for Class III	510(k) / De Novo / PMA; CLIA waiver if applicable	3–6 mo (510k); 12–36 mo (PMA)	\$21,760 (small biz 510k); \$108,800 (std)	None (reference market — FDA is source of reliance)	C	Reference market globally. FDA clearance enables reliance in 60+ countries. Secure FDA approval first to maximize global leverage.

 Latin America

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Argentina	Latin America	ANMAT / INAME	anmat.gob.ar	Class I–IV (Decreto 1490/92)	Inscripción (enrollment)	Certificado de Autorización; CE/FDA basis accepted	IVD registration via INAME; CE reference accepted	6–18 mo	ARS variable (~USD 100–1,000 official rate)	CE MDR; FDA 510(k)/PMA (supporting documentation)	B	CE MDR reduces technical dossier burden. Currency controls complicate fee payment — work with local importer. MERCOSUR harmonization advancing.
Bolivia	Latin America	AGEMED	agemed.gob.bo	Class I–III	Registration notice	Full registration; CE MDR reference accepted	IVD registration through AGEMED	12–24 mo	USD 200–800	CE MDR (supporting documentation)	C	Limited regulatory capacity; long processing times. CE MDR reference helps but independent process required. Local importer essential.
Brazil	Latin America	ANVISA	anvisa.gov.br	Class I–IV (RDC 751/2022)	Notificação (notification)	Cadastro/Registro; IQAS/CE can reduce review	IVD Class III/IV full registration (RDC 769/2022)	6–12 mo (Class II); 12–24 mo (Class III/IV)	BRL 4,000–80,000 (~USD 800–16,000)	CE MDR; FDA PMA (Priority Review credit)	C	Largest LATAM market. IQAS or CE MDR accelerates review. Appoint Brazilian ANVISA holder. Portuguese IFU mandatory. Priority Review pathway available.
Chile	Latin America	ISP (Instituto de Salud Pública)	ispch.cl	Class I–IV (DS 825)	Simple registration	Technical registration; CE/FDA evidence accepted	IVD registration; WHO PQ or CE MDR reference	6–12 mo	CLP 100,000–600,000 (~USD 110–680)	CE MDR; FDA; TGA (supporting documentation)	B	ISP accepts international certifications to reduce review burden. Chile–Pacific Alliance agreement improves regional convergence. Stable regulatory environment.
Colombia	Latin America	INVIMA	invima.gov.co	Class I–IV (Decreto 4725/2005)	Technical Notification (Class I)	Sanitary Registration; CE/FDA expedites	IVD full registration; CE MDR reference	3–6 mo (I/II); 12–24 mo (III/IV)	COP 500,000–5,000,000 (~USD 125–1,250)	CE MDR; FDA 510(k)/PMA	B	INVIMA accepts CE MDR for abbreviated review of Class III/IV. Colombia is IMDRF member — harmonization improving. Growing MedTech hub.
Costa Rica	Latin America	MINSA / DNFD	ministeriodesalud.gob.cr	Class I–III	Notification	Sanitary	IVD registration	6–18 mo	CRC 50,000–	CE MDR; FDA	B	Advanced Central American

Latin America (continued)

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Guatemala	Latin America	MSPAS / DRCA	mepas.gob.gt	Class I–III	Registration	Full national registration; CE/FDA supporting	IVD through MSPAS	6–24 mo	GTQ 500–5,000 (~USD 65–650)	CE MDR; FDA (supporting evidence)	C	Regulatory capacity improving; long delays common. CE/FDA evidence helps but full national process required. Largest Central American economy.
Honduras	Latin America	SESAL / ARSA	arsa.gob.hn	Class I–III	Registration	Sanitary Registration	IVD registration	12–24 mo	HNL 500–5,000 (~USD 20–200)	CE MDR (supporting evidence)	C	Limited regulatory infrastructure. Engage local regulatory consultant; expect extended review timelines. Market growing with CAFTA-DR trade agreement.
Jamaica	Latin America	MOH Jamaica	moh.gov.jm	CE/FDA-referenced (informal system)	Import permit	Registration via MOH; CE/FDA strongly preferred	IVD through MOH	3–12 mo	JMD 10,000–50,000 (~USD 65–325)	CE MDR; FDA 510(k)/PMA (primary basis)	A	MOH relies heavily on FDA/CE clearance as prerequisite. Obtain reference approval first; Jamaica registration is largely administrative. English-speaking Caribbean hub.
Nicaragua	Latin America	MINSA / DGPAF	minsa.gob.ni	Class I–III	Registration	Full national registration	IVD registration	12–24 mo	NIO 2,000–10,000 (~USD 55–275)	CE MDR (occasionally referenced)	C	Political instability affects regulatory consistency. Local partner essential. Low market priority for most manufacturers. CE MDR reference helpful but process is independent.
Panama	Latin America	MINSA / DAFAR	minsa.gob.pa	Class I–III	Registration	Sanitary Registration; CE/FDA accepted	IVD through DAFAR	3–12 mo	USD 300–1,200 (dollarized)	CE MDR; FDA 510(k)/PMA	B	Strategic hub for Central America; free-trade zone advantages. CE MDR or FDA accepted as reliance basis. Gateway to Central American markets.
Paraguay	Latin America	DINAVIS	mspbs.gov.py/dinavis	Class I–III	Notification	Sanitary	IVD registration	6–18 mo	PYG 500,000–	CE MDR; FDA	B	Small MERCOSUR market; CE

EU/EEA												
Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Austria	EU/EEA	BASG / AGES	basg.gv.at	EU MDR Class I–III / IVDR A–D	EUDAMED registration; Class I self-declaration	CE MDR with Notified Body (Class IIa–III)	IVDR Notified Body certification (Class C/D)	3–6 mo (Class I); 12–24 mo (IIb/III)	NB fees EUR 5,000–80,000+ (~USD 5,500–88,000)	CE MDR (single EU-wide certification)	D	CE MDR is mandatory for EU market access. Single CE mark covers all 30 EU/EEA states. BASG oversees national vigilance and market surveillance.
Belgium	EU/EEA	FAMHP (AFMPS)	famhp.be	EU MDR / IVDR	EUDAMED registration; self-declaration Class I	CE MDR with Notified Body	IVDR Notified Body certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	Belgium hosts major Notified Bodies (BSI Belgium, SGS). Strategic EU HQ location; CE mark covers all EU markets simultaneously.
Bulgaria	EU/EEA	BDA (Bulgarian Drug Agency)	bda.bg	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	CE MDR covers Bulgaria as full EU member. Lower-cost manufacturing base; growing MedTech sector. Emerging CE MDR regulatory consulting hub.
Croatia	EU/EEA	HALMED	halmed.hr	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	CE MDR fully applicable. Croatia joined EU Schengen zone 2023. Single CE mark provides full EU/EEA market access including Croatia.
Cyprus	EU/EEA	Ministry of Health Cyprus	moh.gov.cy	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	CE MDR covers Cyprus. Small island market but EU gateway. EUDAMED SRN registration required for market access. English-speaking jurisdiction.
Czech Republic	EU/EEA	SÚKL	sukl.cz	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR Notified Body	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	CE MDR covers Czech Republic. Strong central European MedTech market.

EU/EEA (continued)

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Germany	EU/EEA	BfArM / ZLG	bfarm.de	EU MDR / IVDR	EUDAMED registration; Notified Body via ZLG	CE MDR with Notified Body (TÜV, BSI, etc.)	IVDR Notified Body	12–24 mo (Class IIb/III)	NB fees EUR 10,000–120,000+	CE MDR (EU single market)		Largest EU MedTech market. Germany hosts major Notified Bodies (TÜV SÜD, TÜV Rheinland, DEKRA). CE MDR is market gateway; ideal EU HQ location for global manufacturers.
Greece	EU/EEA	EOF (National Org. for Medicines)	eof.gr	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)		CE MDR covers Greece. Separate notifiable device listing with EOF required for in-market activities. Public hospital procurement significant. Market recovering post-crisis.
Hungary	EU/EEA	OGYÉI (NPHA)	ogyei.gov.hu	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)		CE MDR fully applicable. Growing Central European MedTech manufacturing hub; automotive-to-MedTech transition. Hungarian-language labeling for public procurement.
Iceland	EU/EEA	Lyfjastofnun (Icelandic Med. Agency)	lyfjastofnun.is	EU MDR / IVDR (EEA member)	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EEA — full coverage)		EEA member — CE MDR fully applies. Small but affluent market. Often handled as part of Nordic regional strategy alongside Denmark/Norway.
Ireland	EU/EEA	HPRA	hpra.ie	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body; HPRA oversight	IVDR Notified Body	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)		Premier EU MedTech hub — largest medical device exporter per capita worldwide. HPRA Notified Body active. Post-Brexit EU gateway for UK companies. 9 of world's top 10


EU/EEA (continued)

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Malta	EU/EEA	Medicines Authority Malta	medicinesauthority.gov.mt	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	CE MDR covers Malta. English-speaking EU jurisdiction. Medicines Authority Malta active in EU certification processes. Small island market with growing med-tourism.
Netherlands	EU/EEA	CIBG / Farmatec	farmatec.nl	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR Notified Body	12–24 mo (Class IIb/III)	NB fees EUR 8,000–100,000+	CE MDR (EU single market)	D	CE MDR covers Netherlands. Major EU logistics hub (Rotterdam port); BSI Netherlands NB active. Strong MedTech cluster in Eindhoven/Brainport region.
Norway	EU/EEA	NOMA (Norwegian Medicines Agency)	legemiddelverket.no	EU MDR / IVDR (EEA member)	EUDAMED registration (EEA)	CE MDR with Notified Body	IVDR Notified Body	12–24 mo (Class IIb/III)	NB fees EUR 8,000–100,000+	CE MDR (EEA party — full coverage)	D	EEA member — CE MDR fully applies. Norway also receptive to TGA under informal arrangements. High-income market; strong public health procurement via government tenders.
Poland	EU/EEA	URPL	urpl.gov.pl	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR Notified Body	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	CE MDR covers Poland. Large Central European market (38M population); growing MedTech manufacturing. URPL strict on MDR documentation completeness.
Portugal	EU/EEA	Infarmed	infarmed.pt	EU MDR / IVDR	EUDAMED registration	CE MDR with Notified Body	IVDR certification	12–24 mo (Class IIb/III)	NB fees EUR 5,000–80,000+	CE MDR (EU single market)	D	CE MDR covers Portugal. Portuguese-language IFU links directly to Brazilian ANVISA submission requirements. Infarmed active in EU MDR guidance development.

Europe Non-EU

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Albania	Europe Non-EU	DPM / Ministry of Health	shendetesia.gov.al	CE MDR-aligned classification	Device registration	CE MDR required as technical basis	IVD registration; CE IVDR basis	6–18 mo	ALL 5,000–20,000 (~USD 50–200)	CE MDR (required as technical basis)	B	EU candidate country; CE MDR is de facto prerequisite. Small market; often entered as part of Western Balkans strategy alongside Serbia and N. Macedonia.
Bosnia & Herzegovina	Europe Non-EU	ALMBIH	almbih.gov.ba	CE MDR-aligned classification	Device registration	Registration; CE MDR accepted	IVD registration	6–18 mo	BAM 500–5,000 (~USD 280–2,800)	CE MDR (primary reference)	B	EU candidate; CE MDR is effectively required technical basis. Complex dual political structure may complicate distribution — plan carefully for entity-level requirements.
North Macedonia	Europe Non-EU	MALMED	malmed.gov.mk	CE MDR-aligned (EU harmonizing)	Device registration	Registration; CE MDR accepted as basis	IVD registration	6–18 mo	MKD 5,000–20,000 (~USD 90–360)	CE MDR (primary reference)	B	EU candidate; harmonizing with EU MDR. CE MDR expedites approval. Often grouped with Albania/Serbia in Balkans regional rollout strategy.
Serbia	Europe Non-EU	ALIMS	alims.gov.rs	Class I–III (aligned with EU MDR)	Device listing	Registration; CE MDR required as technical basis	IVD registration; CE IVDR basis accepted	3–12 mo	RSD 5,000–50,000 (~USD 45–460)	CE MDR / IVDR (effectively required)	B	EU candidate country — aligning with EU MDR. CE MDR effectively prerequisite for Serbian registration. ALIMS processes improving steadily with EU integration.
Switzerland	Europe Non-EU	Swissmedic	swissmedic.ch	Class I–III / IVDR Classes (MepV SR 812.213)	Self-declaration Class I + Swissmedic notification	CE MDR required + Swissmedic notification; Swiss CH-REP mandatory	IVDR + Swissmedic notification	4–12 mo (post CE MDR)	CHF 600–5,000 (~USD 680–5,700) + NB fees	CE MDR / IVDR (required as technical basis)	D	CE MDR is prerequisite for Swiss market; Swissmedic notification is layered on top. Swiss Authorized Representative (CH-REP) mandatory. EU-CH MRA currently under renegotiation.

Middle East & North Africa

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Algeria	Middle East & North Africa	ANPP	anpp.dz	CE-aligned classification	Registration	Full national registration; CE reference accepted	IVD registration	18–36 mo	DZD 50,000–200,000 (~USD 370–1,500)	CE MDR (supporting documentation)	C	Large North African market (44M+ population). Bureaucratic and protracted processes; long timelines common. French-language documentation required. Local partner essential.
Bahrain	Middle East & North Africa	NHRA	nhra.bh	CE/FDA-referenced classification	Device listing	Registration; CE MDR or FDA required	IVD registration	3–9 mo	BHD 200–1,000 (~USD 530–2,650)	FDA 510(k)/PMA; CE MDR	A	NHRA accepts CE MDR or FDA as primary registration basis. GCC harmonization drives convergence. Bahrain RegTech hub model being applied to health regulation.
Egypt	Middle East & North Africa	EGMED (Egyptian Drug Authority)	eda.gov.eg	Class I–IV (Law 127/1955 amended)	Registration / listing	Full registration; CE MDR or FDA accepted as supporting evidence	IVD registration via EGMED	12–24 mo	EGP 5,000–50,000 (~USD 100–1,000)	CE MDR; FDA (supporting documentation)	C	Largest Arab market (105M+ population). EGMED actively modernizing. CE MDR reduces dossier burden but full local process required. Arabic IFU mandatory. Local agent required.
Jordan	Middle East & North Africa	JFDA	jfda.jo	Class A–D (aligned with GCC)	Listing / notification	Registration; CE MDR or FDA required	IVD registration	6–18 mo	JOD 200–2,000 (~USD 280–2,820)	FDA 510(k)/PMA; CE MDR	B	JFDA accepts CE MDR and FDA clearance for abbreviated review. Jordan is regional healthcare hub (King Hussein Cancer Center, JUH). Good entry point for Levant region.
Kuwait	Middle East & North Africa	MOH Kuwait / Drugs & MD Affairs	moh.gov.kw	CE/FDA-referenced	Import permit	Registration; CE MDR or FDA clearance required	IVD registration via MOH	6–18 mo	KWD 100–1,000 (~USD 325–3,250)	FDA 510(k)/PMA; CE MDR	A	CE MDR or FDA clearance is de facto prerequisite. GCC harmonization initiative may streamline registration across Gulf states. Strong public

Middle East & North Africa (continued)

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Tunisia	Middle East & North Africa	DHMPE / Ministry of Health	santetunisie.rns.tn	CE-aligned classification	Autorisation de Mise sur Marché	Full registration; CE MDR reference accepted	IVD registration	12–24 mo	TND 500–3,000 (~USD 160–970)	CE MDR (supporting documentation)	C	French-language documentation required. CE MDR reference helps but full national process required. Tunisia is manufacturing hub for European nearshoring. Stable regulatory environment.
UAE	Middle East & North Africa	MOHAP + DHA + DOH Abu Dhabi	mohap.gov.ae	Class I–IV (Cabinet Resolution 66/2020)	HAAD/DHA listing (Class I)	MOH pre-market registration; CE MDR/FDA shortens review	IVD registration; CE IVDR/FDA basis accepted	3–9 mo (with CE/FDA); 12–18 mo (standard)	AED 2,000–20,000 (~USD 545–5,450)	FDA 510(k)/PMA; CE MDR (strong reliance basis)	B	Multiple competent authorities (federal + emirate level). CE MDR or FDA strongly accelerates UAE approval. Strategic MENA hub; annual Arab Health expo. Local agent mandatory.

Sub-Saharan Africa

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Cameroon	Sub-Saharan Africa	DGSN / MINSANTE	minsante.cm	CE-aligned (CEMAC harmonization)	Import authorization	Registration; CE MDR reference accepted	IVD registration	12–30 mo	XAF 100,000–500,000 (~USD 165–825)	CE MDR (primary reference)	C	Bilingual market (French + English). CEMAC harmonization improving. CE MDR reference accepted. Gateway to Central and West African francophone markets.
Ethiopia	Sub-Saharan Africa	EFDA	efda.gov.et	Class I–III	Import permit	Registration; CE/FDA reference accepted	IVD registration	12–24 mo	ETB 2,000–20,000 (~USD 35–350)	CE MDR; WHO PQ (preferred for IVD)	C	2nd most populous African country (120M+). EFDA developing rapidly. CE MDR reference helps. WHO PQ critical for public-sector IVD procurement. Political stability varies by region.
Ghana	Sub-Saharan Africa	FDA Ghana	fdaghana.gov.gh	Class I–III	Product notification	Registration; CE MDR reference accepted	IVD registration	6–18 mo	GHS 500–5,000 (~USD 40–400)	CE MDR; FDA US (supporting documentation)	C	FDA Ghana improving efficiency. CE MDR reference accepted to reduce technical burden. Stable regulatory environment; growing healthcare sector via NHIS.
Ivory Coast	Sub-Saharan Africa	DPM / MSLS	msls.gouv.ci	CE-aligned (WAEMU harmonization)	Import authorization	Registration; CE MDR reference	IVD registration	12–24 mo	XOF 100,000–500,000 (~USD 165–825)	CE MDR (primary reference)	C	Largest francophone West African economy. WAEMU pharma harmonization extending to devices. French-language documentation required. Strategic hub for West Africa.
Kenya	Sub-Saharan Africa	PPB (Pharmacy and Poisons Board)	pharmacyboardkenya.org	Class I–III (PPB regulations)	Product listing	Registration; CE MDR reference accepted	IVD registration via PPB	12–24 mo	KES 10,000–100,000 (~USD 77–770)	CE MDR; FDA (supporting documentation)	C	East African economic hub; PPB improving registration processes. Kenya active in African Medicines Agency (AMA) development. EAC

East Asia

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
China	East Asia	NMPA	nmpa.gov.cn	Class I–III / IVD (Order 739/2021)	Record filing (Class I)	Registration (Class II: provincial; Class III: NMPA national)	IVD Class III: NMPA national; Class II: provincial	12–24 mo (Class II); 24–48 mo (Class III)	CNY 5,000–100,000 (~USD 700–14,000)	None — independent full registration required (GBA pilot limited scope)	C	World's 2nd largest MedTech market. No foreign reliance pathway. China-specific clinical data often required for Class III. Mandatory China-based MAH or local agent. Plan minimum 3-year horizon.
Hong Kong	East Asia	MDCO / DOH	mdco.gov.hk	Class I–IV (MD Ordinance Cap. 359)	Exempt (Class I listed)	Registration; CE MDR or FDA clearance required for Class III/IV	IVD registration; CE IVDR/FDA basis	3–12 mo	HKD 1,000–10,000 (~USD 130–1,280)	FDA 510(k)/PMA; CE MDR; TGA (all accepted)	A	CE MDR or FDA clearance required as prerequisite for Class III/IV. SAR with own registration system separate from mainland China. Gateway to China market.
Japan	East Asia	PMDA / MHLW	pmda.go.jp	Class I–IV / IVD (PMD Act 2014)	Self-certification (Todokede) Class I	PMDA review (Ninsho); 3rd-party Nintei for Class II	PMDA for IVD Class III/IV; Nintei for Class II	12–18 mo (Class II); 18–36 mo (Class III/IV)	JPY 300,000–5,000,000 (~USD 2,000–34,000)	No formal reliance; FDA/CE data accepted as supporting evidence	C	World's 3rd largest MedTech market. Japan-specific clinical data often required for Class III. MAH in Japan mandatory; consider AMED early engagement program. QMS audit (MHLW) required.
South Korea	East Asia	MFDS	mfds.go.kr	Class I–IV / IVD (Medical Devices Act 2004)	Notification (Class I)	Certification (Class II); Permit (Class III/IV); CE/FDA data accepted	IVD certification / permit by class	3–6 mo (Class II); 12–18 mo (Class III/IV)	KRW 1,000,000–20,000,000 (~USD 750–15,000)	FDA 510(k)/PMA; CE MDR (abbreviated review pathway available)	B	FDA or CE MDR clearance enables abbreviated MFDS review for Class III/IV. MFDS among Asia's most efficient regulators. Korean-language IFU required. Strategic tech market.
Taiwan	East Asia	TFDA (Taiwan FDA)	fda.gov.tw	Class I–III / IVD (Medical Device Act 2021)	Class I registration	TFDA review; FDA/CE MDR enables abbreviated review	IVD registration; Class III: full review	3–6 mo (Class II); 12–18 mo (Class III)	TWD 5,000–100,000 (~USD 160–3,200)	FDA 510(k)/PMA; CE MDR (abbreviated review pathway)	B	FDA or CE clearance enables abbreviated review process. TFDA one of Asia's most efficient agencies. Separate

South Asia

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Bangladesh	South Asia	DGDA	dgda.gov.bd	CE/WHO-referenced	Import permit	Registration; CE MDR / WHO PQ reference accepted	IVD registration; WHO PQ preferred	12–24 mo	BDT 5,000–50,000 (~USD 45–460)	CE MDR; WHO PQ (priority for public procurement)	C	Growing market; DGDA developing regulatory capacity. WHO PQ or CE MDR reference accepted. Local importer mandatory. Garment-to-healthcare sector transition creating demand.
India	South Asia	CDSCO	cdsco.gov.in	Class A–D (MD Rules 2017)	Import/manufacturing licence (Form MD-14/15)	Registration Certificate (Form MD-15); CE/FDA reduces Class C/D review	IVD registration under MD Rules; separate IVD guidance	3–6 mo (A/B); 12–18 mo (C/D)	INR 5,000–500,000 (~USD 60–6,000)	CE MDR; FDA 510(k)/PMA (accepted for abbreviated Class C/D review)	B	Rapidly growing market (1.4B population). CDSCO accepts CE/FDA for shortened Class C/D review. In-country testing sometimes required. CDSCO e-portal improving significantly.
Nepal	South Asia	DoDA (Dept. Drug Administration)	doanepal.gov.np	WHO-referenced	Registration	Registration; WHO PQ or CE MDR reference	IVD registration	12–24 mo	NPR 5,000–30,000 (~USD 37–225)	CE MDR; WHO PQ; Indian CDSCO registration	C	Indian CDSCO registration often a practical prerequisite given supply chain dependency. CE MDR reference accepted. Small market; combined with India strategy for efficiency.
Pakistan	South Asia	DRAP	dra.gov.pk	Class A–D (MD Rules 2017)	Import licence	Registration; CE MDR reference accepted	IVD registration	12–24 mo	PKR 10,000–200,000 (~USD 35–720)	CE MDR; FDA (supporting documentation)	C	Large market (230M+ population). DRAP processes slower than India; CE/FDA reference helps. Economic volatility affects market access and currency conversion for fees.
Sri Lanka	South Asia	NMRA	nmra.gov.lk	Class A–D	Registration	Registration; CE MDR reference accepted	IVD registration	6–18 mo	LKR 5,000–50,000 (~USD 15–155)	CE MDR; FDA (supporting documentation)	B	NMRA improving after economic crisis period. CE MDR reference significantly eases review. Small but stable

Southeast Asia

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Brunei	Southeast Asia	MOH Brunei / Pharmacy Board	moh.gov.bn	CE/FDA-referenced	Import license	Registration; CE MDR or FDA required	IVD via MOH Brunei	3–12 mo	BND 200–1,000 (~USD 150–745)	CE MDR; FDA (de facto prerequisite)	A	Small, wealthy market. CE MDR or FDA clearance effectively required for registration. Often handled as extension of Malaysia/Singapore regulatory strategy.
Cambodia	Southeast Asia	MAPH / MOH Cambodia	moh.gov.kh	WHO-referenced	Import permit	Registration; CE MDR reference accepted	IVD registration	6–18 mo	USD 200–1,000	CE MDR; FDA (supporting documentation)	B	Developing regulatory framework; CE MDR or FDA reference greatly eases approval. Growing healthcare investment driven by tourism economy and diaspora remittances.
Indonesia	Southeast Asia	BPOM	pom.go.id	Class I–III (Permenkes 62/2017)	Notification (Class I)	Registration; CE MDR/FDA basis for abbreviated Class III review	IVD registration; Class III IVD: full BPOM review	3–6 mo (Class II); 12–24 mo (Class III)	IDR 1,000,000–10,000,000 (~USD 65–650)	CE MDR; FDA (abbreviated review pathway for Class III)	B	4th most populous country (280M+). BPOM accepts CE MDR for abbreviated Class III review. Local PT importer required. ASEAN CSDT compatible. Growing domestic device industry.
Laos	Southeast Asia	FDA Laos / MOH	fda.gov.la	WHO-referenced	Import authorization	Registration; WHO PQ or CE MDR reference	IVD registration	12–24 mo	USD 200–600	CE MDR; WHO PQ (preferred)	C	Very limited regulatory capacity. CE MDR or WHO PQ reference helpful. Small market; typically entered only as part of broader ASEAN regional strategy.
Malaysia	Southeast Asia	MDA (Medical Device Authority)	mda.gov.my	Class A–D (Medical Device Act 2012)	Registration (Class A: simple listing)	Registration; CE MDR or FDA basis accepted	IVD registration; IVDR/FDA basis	1–6 mo (A/B); 6–18 mo (C/D)	MYR 200–5,000 (~USD 45–1,120)	FDA 510(k)/PMA; CE MDR; TGA (abbreviated review pathway)	B	MDA accepts CE MDR/FDA for abbreviated Class C/D review. Malaysia is a major MedTech manufacturing hub (Penang).

EAEU Bloc

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Armenia	EAEU Bloc	State Health Inspectorate	healthinspect.am	EAEU Class 1–3 / IVD	EAEU registration	EAEU registration; CE MDR data supporting	EAEU IVD registration	12–24 mo	AMD 50,000–500,000 (~USD 130–1,300)	CE MDR; FDA (supporting only in EAEU process)	C	EAEU member but more Western-oriented than Russia/Belarus. CE MDR data eases technical review. Armenia increasingly used as gateway to EAEU market without Russia sanctions exposure.
Belarus	EAEU Bloc	RERC (RUE Center of Expertise)	rceth.by	EAEU Class 1–3 / IVD	EAEU registration	EAEU registration	EAEU IVD registration	12–24 mo	BYN 500–5,000 (~USD 155–1,550)	CE MDR; FDA (supporting only)	C	Sanctions and political situation restrict Western manufacturer access. EAEU process required. Market access severely limited post-2020. Legal compliance review mandatory.
Kazakhstan	EAEU Bloc	DKMD / NDDA	ndda.kz	EAEU Class 1–3 / IVD	EAEU registration	EAEU registration; CE/FDA data accepted as supporting	EAEU IVD registration	12–24 mo	KZT 50,000–500,000 (~USD 110–1,100)	CE MDR; FDA (supporting only — EAEU process required)	C	EAEU registration covers Kazakhstan. Geographically strategic Central Asia hub. CE/FDA data helps reduce technical burden but full EAEU process required. Less sanctions exposure than Russia.
Kyrgyzstan	EAEU Bloc	CDMP	cdmp.gov.kg	EAEU Class 1–3 / IVD	EAEU registration	EAEU registration	EAEU IVD registration	12–24 mo	KGS 5,000–50,000 (~USD 57–575)	CE MDR; FDA (supporting only)	C	EAEU member with limited regulatory capacity. Small market; typically registered as part of EAEU bundle strategy through Kazakhstan or Armenia as primary country.
Russia	EAEU Bloc	Roszdravnadzor	roszdravnadzor.gov.ru	EAEU Class 1–3 / IVD (EAEU Decision)	EAEU Medical Device	EAEU registration (Roszdravnadzor)	EAEU IVD registration	12–24 mo	RUB 50,000–500,000 (~USD 500–5,000)	CE MDR/FDA as supporting data	C	Sanctions (2022+) severely restrict Western manufacturer

Pacific & Oceania

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Australia	Pacific & Oceania	TGA	tga.gov.au	Class I–III / IVD 1–4 (Therapeutic Goods Act 1989)	ARTG listing (Class I); self-certification	ARTG registration (IIa–III); conformity assessment or NB cert	IVD: ARTG listing (Class 1/2) or registration (Class 3/4)	1–3 mo (Class I/IVD1); 6–12 mo (Class III); 12–24 mo (high-risk III)	AUD 800–15,000 (~USD 530–10,000)	FDA 510(k)/PMA; CE MDR (TGA accepts as basis for conformity assessment)	B	TGA accepts CE MDR or FDA as basis for Australian conformity assessment — no separate NB recertification needed. ARTG inclusion straightforward. TGA certification accepted by Singapore HSA, NZ Medsafe, and Pacific nations.
Fiji	Pacific & Oceania	Fiji Pharmaceutical & Biomedical Service	health.gov.fj	TGA/WHO-referenced	Import permit	Registration; TGA/CE reference accepted	IVD via MOH Fiji	3–12 mo	FJD 200–1,000 (~USD 90–450)	TGA; CE MDR; FDA (primary reference)	A	TGA or CE MDR effectively required. Very small Pacific island market; typically registered as part of Australia/Pacific regional strategy. Medical tourism from Pacific islands significant.
New Caledonia	Pacific & Oceania	DASS / ANSES (French oversight)	dass.gouv.nc	EU MDR (French overseas territory)	CE MDR (French territory)	CE MDR with Notified Body	IVDR certification	12–24 mo (via CE MDR)	NB fees EUR 5,000–80,000+	CE MDR (required — French territory)	D	French overseas territory — EU MDR/CE MDR applies directly. If CE MDR obtained for EU, New Caledonia is automatically covered. No additional registration step needed.
New Zealand	Pacific & Oceania	Medsafe	medsafe.govt.nz	Class I–IIb / IVD (HSNO Act / Medicines Act)	WAND database listing	WAND registration; CE MDR or TGA certification accepted	IVD via WAND; CE IVDR or TGA accepted	1–6 mo	NZD 200–2,000 (~USD 125–1,250)	CE MDR; TGA; FDA (Medsafe accepts as primary reliance basis)	A	Medsafe fully relies on CE MDR/TGA/FDA. Obtain reference approval; NZ registration is largely administrative. Trans-Tasman framework with Australia accelerating harmonization.
Papua New Guinea	Pacific & Oceania	TGA PNG / NDOH	health.gov.pg	TGA/WHO-	Import	Registration: TGA	IVD registration	6–18 mo	PGK 500–3,000	TGA: CE MDR (de	A	TGA Australia certification

Other

Country	Region	Reg. Authority	Agency URL	Classification	Pathway (Class I)	Pathway (Class II/III)	Pathway (IVD)	Timeline	Est. Fees (USD)	Reliance Accepted	Approach	Key Strategic Note
Afghanistan	Other	Ministry of Public Health (MoPH)	moph.gov.af	Minimal formal regulatory system	Import authorization (informal)	No structured pre-market approval system exists	No formal IVD regulation	Indefinite / unpredictable	Minimal	None	E	No functioning commercial medical device regulatory framework. Humanitarian access only; not viable for commercial registration under current governance. Engagement via NGO/humanitarian channels only.
Iran	Other	IMED (Iran Medical Device Directorate)	imed.ir	Class 1–4 (National regulation)	Registration	Full national registration; CE MDR/FDA as supporting only	IVD registration	12–36 mo	IRR (variable due to hyperinflation)	CE MDR; FDA (supporting only — limited formal reliance)	E	US + EU sanctions severely limit Western manufacturer access. Large market (85M+ population) but regulatory and sanctions environment is prohibitive. Humanitarian exceptions apply for some devices.
Iraq	Other	Iraqi MOH / CDCSO	moh.gov.iq	CE/WHO-referenced	Import permit	Registration; CE MDR or FDA required	IVD registration via MOH Iraq	12–24 mo	USD 500–3,000	CE MDR; FDA (de facto prerequisite)	E	Security situation and bureaucratic complexity make market access challenging. CE MDR or FDA clearance required. Experienced local partner essential. Market improving but infrastructure still rebuilding.
Israel	Other	AMAR (MOH Israel)	health.gov.il	Class I–IV (Medical Devices Law 2012)	Registration	Registration; FDA 510(k)/PMA or CE MDR enables abbreviated process	IVD registration; CE IVDR/FDA basis accepted	3–9 mo (with FDA/CE); 12–24 mo (without)	ILS 2,000–20,000 (~USD 550–5,500)	FDA 510(k)/PMA; CE MDR (strong abbreviated pathway)	B	AMAR accepts FDA or CE MDR for significantly abbreviated review. Active MedTech ecosystem (Start-Up Nation). EU-Israel regulatory alignment agreement under ongoing negotiation.

Methodology & How to Use This Guide

Data Collection: This report synthesizes regulatory intelligence from official agency websites, IMDRF guidance documents, WHO regulatory system assessments, RegDesk platform data, and regulatory affairs expertise. Priority markets (top 30) were researched against published agency guidance; remaining markets were assessed based on regulatory system alignment and membership in international harmonization initiatives (IMDRF, GHTF, ASEAN CSDT, EAEU, GCC, EAC, WAEMU, CEMAC).

Best Approach Assignment: Each country's approach code (A–F) was assigned based on: (1) published reliance policy, (2) regulatory authority statements on international certification recognition, (3) typical registration timelines reported by manufacturers, (4) regulatory system maturity score, and (5) IMDRF membership and harmonization commitments.

Fee Data: Fees represent government/agency fees only and exclude Notified Body fees, local representative costs, translation costs, and consulting fees. Actual total costs may be 3–10× higher. Currency conversions use July 2026 approximate rates.

Timeline Data: Timelines represent median review timelines under normal conditions. Political, economic, or backlog conditions can extend timelines significantly. Priority/expedited pathways may reduce timelines where available.

⚠ Important Disclaimer

This report is for strategic planning purposes only and does not constitute legal or regulatory advice. Medical device regulations change frequently. Always verify current requirements with the relevant competent authority or qualified regulatory affairs professional before submitting any application. RegDesk recommends subscribing to the RegDesk Platform for real-time regulatory updates.

Approach Code Quick Reference

A	Direct Reliance Country fully accepts FDA 510(k)/PMA, CE MDR, or TGA as basis. Submit reference + local docs. Typical: 2–6 months.
B	Abbreviated Registration Accelerated review based on CE/FDA/TGA but still requires local submission. Typical: 3–12 months.
C	Full Independent No recognized reliance. Full technical dossier; local testing may be required. Typical: 12–36 months.
D	CE MDR First, Then Expand CE MDR is the most efficient gateway for this market. Prioritize CE; then use for regional reliance.
E	Local Partner / In-Country Requires local authorized representative, in-country testing/QMS audit, or significant local partnership.
F	Notification Only Simple notification or listing; no pre-market approval required. Fastest pathway.

Data Sources & Cutoff

- Official regulatory agency websites and published guidance
- IMDRF, WHO, GHTF harmonization documents
- RegDesk regulatory intelligence database
- EUDAMED public registry
- ASEAN CSDT technical dossier guidelines
- Data cutoff: July 2026