

REGDESK REGINTEL REPORT

Global Medical Device Regulatory Pathways, Timelines & Fees



Based on RegDesk RegIntel Data

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Coverage: 128 countries | Medical Devices only

Data Source: RegDesk RegIntel Database

Scope note: Fees and timelines are indicative ranges based on RegIntel data. Verify current requirements with the competent authority before submission.

Country	Classifications	Registration Pathway	Fees	Est. Timeline	Agency
Algeria	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 0	0 months	Agence Nationale des Produits Pharmaceutiques
Argentina	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Wireless Device (WLD)	USD 150–200 / USD 190–258 / USD 243–340	1–2 months / 3–6 months / 0 months	ANMAT- Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica
Armenia	N/A	Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0 / USD 0–20	0 months / 0–1 months	Scientific Center of Drug and Medical Technology Expertise
Azerbaijan	N/A	Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	0 months	Analytical Expertise Center
Australia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Electromagnetic Compatibility (EMC)	USD 1,000–5,000 / USD 2,500–7,500 / USD 2,500–8,000	0–1 months / 1–2 months / 2–3 months	Therapeutic Goods Administration
Austria	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	Austrian Medicines Agency - Medical Device Agency - Austrian Federal Office for Safety in Health Care
Bahrain	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Wireless Device (WLD); Importation (IMP)	USD 53–107 / USD 398–400 / USD 398–796	0–1 months / 2–4 months / 0 months	National Health Regulatory Authority; Pharmacovigilance Product Regulatory Authority
Bangladesh	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 700–800 / USD 0	0–1 months / 3–4 months / 4–6 months	Directorate General of Administration

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Cameroon	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 0–100 / USD 0	0 months	Ministry of Public Health
Canada	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 8,272 / USD 410 / USD 5,810	4–5 months / 1–2 months / 2–3 months	Health Canada
Chile	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Post Market Surveillance (VIG) and Recalls	USD 0–350 / USD 0	0–2 months / 0–12 months / 0 months	Ministry of Health - Institute of Public Health
China	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Wireless Device (WLD)	USD 10–15,000 / USD 50,000–80,000 / USD 0–5,000	0–1 months / 12–24 months / 12–20 months	China National Medical Products Administration
Colombia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Post Market Surveillance (VIG) and Recalls	USD 0–800 / USD 0–850 / USD 0–950	0–1 months / 4–6 months / 0 months	National Food and Drug Surveillance Institute (INVIMA)
Costa Rica	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 0 / USD 0–5,000 / USD 0–50	0 months / 6–8 months / 0–1 months	Ministerio de Salud

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Ethiopia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Post Market Surveillance (VIG) and Recalls	USD 0	0 months	Ethiopian Food and Drug Authority
European Union	N/A	N/A	N/A	N/A	N/A
Finland	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	Finnish Medicines Agency
France	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	National Agency for the Safety of Medicine and Health Products
Georgia	N/A	Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	0 months	LEPL Medical and Pharmaceutical Activities Regulation Agency
Germany	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	Federal Institute for Drugs and Medical Devices
Ghana	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Wireless Device (WLD); Software (SW)	USD 50–60 / USD 80–100 / USD 150–160	0–12 months / 0 months / 0–1 months	Food and Drugs Authority
Greece	N/A	Medical Device (MD); In Vitro Diagnostic (IVD)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	Greek National Organization for Medicines (EOF)

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Ireland	N/A	In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED); Electromagnetic Compatibility (EMC)	USD 0	0 months / 3–6 months	Health Products Regulatory Authority (HPRA)
Israel	N/A	Medical Device (MD); Wireless Device (WLD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 0–5,000 / USD 0 / USD 700	6–8 months / 1–2 months / 0 months	Medical Device Division of the Israeli Ministry of Health (AMAR)
Italy	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	Italian Medicines Agency
Ivory Coast	N/A	Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	0 months	N/A
Jamaica	N/A	Medical Device (MD); Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0–40 / USD 0	0 months	Ministry of Health & Wellness
Japan	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Wireless Device (WLD)	USD 5,000–15,000 / USD 30,000–50,000 / USD 50,000–70,000	0–1 months / 3–9 months / 6–9 months	Pharmaceuticals and Medical Devices Agency (PMDA)
Jordan	N/A	Medical Device (MD); Wireless Device (WLD); Importation (IMP)	USD 140–214 / USD 35–260 / USD 0	1–2 months / 0–1 months / 0 months	Jordan Food and Drug Administration
Kazakhstan	N/A	Medical Device (MD); Importation (IMP); Establishment License (ESL)	USD 0	0–11 months / 0 months	National Center for Expertise of Medicines and Medical Devices
Kenya	N/A	Medical Device (MD); In Vitro Diagnostic	USD 100 / USD 100–200 / USD 500–1,000	0–3 months / 3–5 months / 0 months	Pharmacy and Poisons Board

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Lithuania	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	State Medicines Control Agency
Luxembourg	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	Ministry of Health
Malaysia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 0–5,000 / USD 10,000–30,000 / USD 15,000–30,000	1–2 months / 3–4 months / 6–7 months	Medical Device Authority, Ministry of Health, Malaysia
Maldives	N/A	Medical Device (MD); Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	0 months	N/A
Malta	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 0	0 months / 3–6 months	Medicines Authority
Mauritius	N/A	Radiation Emitting Devices (RED); Wireless Device (WLD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 0 / USD 0–60	0 months / 1–4 months	Ministry of Health and Wellness
Macedonia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Post Market Surveillance (VIG) and Recalls	USD 0	0 months / 0–3 months	Ministry of Health
Mexico	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 600 / USD 900 / USD 1,100	4–10 months / 0 months / 0–2 months	COFEPRIS

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Nicaragua	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 0	0 months	MINSA
Nigeria	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Wireless Device (WLD); Post Market Surveillance (VIG) and Recalls	USD 0–700 / USD 0 / USD 0–150	0–4 months / 0 months	National Agency for Food and Drug Administration and Control (NAFDAC)
North Macedonia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Post Market Surveillance (VIG) and Recalls	USD 0	0 months / 0–3 months	Ministry of Health
Norway	N/A	Combination Device (CD); Radiation Emitting Devices (RED); Electromagnetic Compatibility (EMC); Wireless Device (WLD)	USD 0	0 months / 3–6 months	The Norwegian Medicines Agency
Oman	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Wireless Device (WLD)	USD 0 / USD 130–260	0 months / 0–1 months	Ministry of Health
Pakistan	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Wireless Device (WLD); Post Market Surveillance (VIG) and Recalls	USD 18–20 / USD 89–90 / USD 178–180	6–9 months / 1–2 months / 0 months	Drug Regulatory Authority of Pakistan (DRAP)
Palestinian Territory	N/A	N/A	N/A	N/A	N/A
Panama	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 350–1,000 / USD 0	0–2 months / 0 months	MINSA Ministry of Health
Paraguay	N/A	Medical Device (MD); Post	USD 0	0 months	Ministry of Public Health

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Russian Federation	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Post Market Surveillance (VIG) and Recalls	USD 0–800 / USD 0–1,000 / USD 0–1,300	0–3 months / 1–2 months / 0 months	Federal Service for Surveillance in Healthcare
Rwanda	N/A	Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	0 months	N/A
Saudi Arabia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Wireless Device (WLD)	USD 3,990–4,000 / USD 5,055–5,100 / USD 5,500–5,600	1–2 months / 0 months / 0–1 months	Saudi Food & Drug Authority
Serbia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Wireless Device (WLD)	USD 0	0–1 months / 0 months	Medicines and Medical Devices Agency of Serbia
Singapore	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Software (SW)	USD 1,000–5,000 / USD 2,900–4,800 / USD 4,500–6,600	0–1 months / 6–8 months / 10–11 months	Health Sciences Authority (HSA)
Slovakia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD); Radiation Emitting Devices (RED)	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	State Institute for Drug Control
Slovenia	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Combination Device (CD);	USD 5,000–15,000 / USD 15,000–30,000 / USD 30,000–50,000	3–9 months / 0 months / 3–6 months	Agency for Medicinal Products and Medical Devices of the Republic of Slovenia

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Tanzania	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Radiation Emitting Devices (RED); Wireless Device (WLD)	USD 0	0–9 months / 0 months	Tanzania Medicines and Medical Devices Authority (TMDA)
Thailand	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 60 / USD 0	0 months	Thai Food and Drug Administration (TFDA)
Tunisia	N/A	Medical Device (MD); Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	0–1 months / 0 months	Ministry of Health
Turkey	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance (VIG) and Recalls; Importation (IMP)	USD 0 / USD 180	1–4 months / 0 months / 1–3 months	Turkish Medicines and Medical Devices Agency (TITCK)
Turkmenistan	N/A	Medical Device (MD); Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	5–6 months / 0 months	Ministry of Healthcare and Medical Industry
Uganda	N/A	Medical Device (MD); Post Market Surveillance (VIG) and Recalls; Importation (IMP); Establishment License (ESL)	USD 0	0 months	National Drug Authority
Ukraine	N/A	Medical Device (MD); In Vitro Diagnostic (IVD); Post Market Surveillance	USD 0	0 months	State Service of Ukraine on Medicines and Drugs Control