



REGULATORY INTELLIGENCE · JUNE 2026

Global AI Legislation Report

Medical Device & General AI Regulatory Frameworks

25+

Jurisdictions
Covered

10+

With Enacted
MD AI Regulation

8+

With General
AI Laws

Executive Summary

25+

Total Jurisdictions Covered

10+

Jurisdictions with Enacted MD AI Regulation

8+

Jurisdictions with General AI Laws

Artificial Intelligence is rapidly transforming medical device development and healthcare delivery worldwide. Regulatory authorities across major markets have responded with dedicated guidance documents, legislation, and cross-sector frameworks that collectively define the global compliance landscape for AI-enabled medical devices. This report synthesizes the current state of AI regulation across **25+ jurisdictions**, spanning both medical device-specific AI legislation and broader cross-sector AI governance frameworks.

As of June 2026, the regulatory environment is characterised by rapid evolution: the EU AI Act has fully applied to high-risk medical devices; the US FDA has issued multiple rounds of guidance including the Predetermined Change Control Plan (PCCP) framework and AI-enabled device action plan; South Korea's Digital Medical Products Act took effect in January 2025; and Brazil enacted RDC 925/2026 introducing adaptive AI requirements. Meanwhile, several jurisdictions — including Canada (Bill C-27) and Colombia — remain in active legislative development.

International bodies including IMDRF and WHO have also published key reference documents (IMDRF GMLP N88, January 2025; WHO AI for Health, 2023) that are shaping harmonised approaches to AI transparency, safety monitoring, and post-market surveillance.

HOW TO READ THIS REPORT

This report is structured in two tracks:

Section 1 — Medical Device AI Legislation: Covers regulations, guidance documents, and frameworks specifically addressing AI/ML-enabled medical devices and Software as a Medical Device (SaMD). These instruments directly govern product classification, pre-market review, post-market surveillance, and labelling requirements for AI-powered medical technologies.

Section 2 — General AI Legislation: Covers cross-sector AI laws and national strategies that are not medical-device-specific but may have significant healthcare implications — including risk classification frameworks, transparency obligations, and high-risk AI provisions that may apply to health AI systems.

Status badges:  **Enacted**  **Draft**  **In Progress**  **None**

Section 1 — Medical Device AI Legislation

This section covers regulatory instruments specifically addressing artificial intelligence and machine learning in medical devices and Software as a Medical Device (SaMD). These instruments govern pre-market approval, product classification, post-market surveillance, and labelling for AI-enabled medical technologies across 20+ jurisdictions. Data current as of June 2026.

Country	Authority	Instrument Name	Status	Year	Scope / Key Provisions	Reference URL
EU	European Commission / European Parliament	EU AI Act — Annex III High-Risk (Medical Devices)	✓ Enacted	2024	Classifies AI systems used in medical devices as high-risk; conformity assessment, transparency, human oversight obligations.	eur-lex.europa.eu
EU	European Commission	EU MDR 2017/745 (AI/ML provisions)	✓ Enacted	2017/2021	Applies to software and AI as medical devices; GSPR requirements for ML-based devices; ongoing MDR revision discussions.	—
USA	FDA	AI-Enabled Device Action Plan & Guidance (Draft 2025)	Draft	2025	Defines lifecycle management for AI/ML-based SaMD; transparency, bias monitoring, real-world performance.	—
USA	FDA	Predetermined Change Control Plan (PCCP) — Final Guidance	✓ Enacted	2024	Allows manufacturers to pre-specify modifications to AI/ML models post-approval; reduces re-submission burden.	—
USA	FDA	Good Machine Learning Practice (GMLP) / AI Transparency	✓ Enacted	2021–2023	10 guiding principles for GMLP developed with Health Canada and TGA; AI transparency discussion paper.	—
UK	MHRA	SaMD / AIaMD Guidance (Multiple)	✓ Enacted	2021–2023	Software and AI as Medical Device Change Programme; guidance on clinical risk classification, IVD AI provisions.	—
Canada	Health Canada	ML-Enabled Medical Device Guidance — Final	✓ Enacted	Apr 2026	Final guidance on ML-enabled devices; covers algorithm transparency, change management, and real-world performance monitoring.	—

Continued on next page — rows 8 onward

Section 1 — Medical Device AI Legislation (continued)

Country	Authority	Instrument Name	Status	Year	Scope / Key Provisions	Reference URL
Canada	Health Canada	Predetermined Change Control Plans (PCCPs) — Accepted	✓ Enacted	Oct 2024	Health Canada accepts PCCPs for AI/ML-enabled devices; aligned with FDA/TGA frameworks.	—
Australia	TGA	SaMD / AI Device Classification — Fully Active	✓ Enacted	Nov 2024	Updated classification framework for SaMD/AI devices fully operational; risk-based approach aligned with IMDRF.	—
South Korea	MFDS	Digital Medical Products Act (effective Jan 24, 2025)	✓ Enacted	2025	Comprehensive legislation covering AI-enabled medical devices; adaptive algorithms, real-world performance monitoring.	—
South Korea	MFDS	Generative AI Medical Device Guidelines	✓ Enacted	2024	Guidelines specifically addressing generative AI in medical devices; transparency and clinical validation requirements.	—
Japan	PMDA / MHLW	PMD Act SaMD Provisions (Revised Mar 2023)	✓ Enacted	2023	Revised Pharmaceutical and Medical Device Act provisions for SaMD; post-approval change management.	—
Japan	PMDA / MHLW	PACMP / IDATEN Adaptive AI Framework	✓ Enacted	2023	Post-Approval Change Management Protocol for AI/ML devices; IDATEN framework for iterative algorithm updates.	—

Additional jurisdictions continued on next page

Section 1 — Medical Device AI Legislation (continued)

Country	Authority	Instrument Name	Status	Year	Scope / Key Provisions	Reference URL
China	NMPA	AI Medical Device Guidelines (6 Guidelines, 2023)	✓ Enacted	2023	Six technical guidance documents covering AI medical device development, testing, clinical evaluation, and post-market.	—
China	NMPA	NMPA Regulations Amended (Dec 2024)	✓ Enacted	Dec 2024	Amendments to AI medical device registration regulations; updated requirements for algorithm transparency and traceability.	—
Singapore	HSA	AI-Enabled Medical Device Guidance	✓ Enacted	2021–2023	Guidance on AI/ML SaMD submissions; aligned with IMDRF GMLP; transparency and post-market surveillance requirements.	—
Taiwan	TFDA	AI Device Review Guidelines (2023)	✓ Enacted	2023	Technical review guidelines for AI-enabled medical devices; clinical performance validation and post-market monitoring.	—
Malaysia	MDA	SaMD Guidance (IMDRF-Aligned)	✓ Enacted	2022–2023	SaMD guidance aligned with IMDRF frameworks; covers AI/ML software classification and registration requirements.	—
Saudi Arabia	SFDA	SaMD Guidance (2022–2023)	✓ Enacted	2022–2023	Software as a Medical Device guidance covering AI-enabled products; risk classification and registration pathway.	—
UAE	DHA / DOH	AI in Healthcare Framework	✓ Enacted	2023	Dubai Health Authority and Department of Health AI governance framework; covers AI medical devices and healthcare AI ethics.	—
Israel	AMAR	SaMD Regulation (Aligned FDA/EU)	✓ Enacted	2022–2023	Israeli medical device authority SaMD framework aligned with FDA and EU MDR; covers AI/ML medical software.	—
Brazil	ANVISA	RDC 657/2022 — Software as Medical Device	✓ Enacted	2022	Defines regulatory framework for software as medical device; establishes classification and registration requirements.	—
Brazil	ANVISA	RDC 751/2022 — SaMD Technical Requirements	✓ Enacted	2022	Technical requirements for SaMD including AI-enabled devices; cybersecurity and software lifecycle requirements.	—
Brazil	ANVISA	RDC 925/2026 — Adaptive AI & Local Data Requirements	✓ Enacted	2026	New regulation for adaptive AI medical devices; requires local data validation and real-world performance monitoring.	—
Brazil	CFM	Resolution CFM 2.454/2026 — AI in Clinical Practice	✓ Enacted	2026	Federal Council of Medicine resolution on AI use in clinical practice; physician accountability and disclosure requirements.	—
Mexico	COFEPRIS	Mexican Pharmacopoeia 5th Ed. — SaMD Provisions (Jul 2023)	✓ Enacted	2023	SaMD provisions within the Mexican Pharmacopoeia; classification and technical requirements for AI-enabled medical software.	—
Mexico	COFEPRIS	SaMD Guide (Dec 2023)	✓ Enacted	2023	Dedicated SaMD guidance document; AI/ML device submission requirements and post-market surveillance obligations.	—
Mexico	COFEPRIS / SSA	NOM-241 + 2024 Amendment (Medical Devices)	✓ Enacted	2024	Good Manufacturing Practice standard for medical devices; 2024 amendment addresses software and AI considerations.	—
Colombia	INVIMA	IMDRF Membership (Sep 2025) — In Progress	🔄 In Progress	2025	Colombia joined IMDRF in September 2025; SaMD and AI guidance framework under development following IMDRF principles.	—
Argentina	ANMAT	Disposition 2318/2022 — SaMD Regulation	✓ Enacted	2022	ANMAT disposition establishing framework for software as medical device classification and registration.	—
International	IMDRF	GMLP N88 — Good Machine Learning Practice (Jan 2025)	✓ Enacted	Jan 2025	International consensus document on GMLP principles for medical AI; benchmark for global regulatory harmonisation.	—
International	WHO	Regulatory Considerations on AI for Health (Oct 2023)	✓ Enacted	2023	WHO guidance on regulatory frameworks for AI health products; risk-proportionate oversight recommendations.	—
International	WHO	Ethics & Governance of AI for Health (2021)	✓ Enacted	2021	WHO ethical principles for AI in health; foundation for national regulatory frameworks worldwide.	—

Section 2 — General AI Legislation (Non-Medical Device Specific)

The following cross-sector AI laws and national strategies are **not medical-device-specific**, but may carry significant healthcare implications — including risk-classification frameworks, transparency obligations, and high-risk AI provisions that may apply to health AI systems, clinical decision support, and hospital AI infrastructure.

Country/Region	Authority	Instrument Name	Status	Year	Healthcare Implications	Reference URL
EU	European Commission / Parliament	EU AI Act — General Provisions (Cross-Sector)	✓ Enacted	2024	Risk-based framework for all AI systems; high-risk classification includes health AI; transparency, accountability obligations.	eur-lex.europa.eu
USA	White House / HHS	Biden EO 14110 on Safe AI (RESCINDED Jan 2025)	🔄 In Progress	2023 → 2025	Rescinded by Trump Administration Jan 2025; health AI provisions no longer enforceable; some sector-specific guidance remains.	www.federalregister.gov
USA	White House	Trump AI Executive Order — Voluntary Framework (Jan 2025)	🔄 In Progress	Jan 2025	Voluntary AI governance framework; deregulatory approach; health AI remains under FDA jurisdiction for device-specific regulation.	www.federalregister.gov
UK	DSIT / CDEI	AI Regulation White Paper (Mar 2023)	🔄 In Progress	2023	Principles-based, sector-led approach to AI regulation; healthcare AI governed through existing MHRA/NHS frameworks.	www.gov.uk
UK	DSIT	UK AI Opportunities Action Plan (Jan 2025)	✓ Enacted	Jan 2025	National AI strategy with NHS/health AI investment priorities; accelerated AI adoption in healthcare settings.	www.gov.uk
China	CAC / MOST	Generative AI Interim Measures (Aug 2023)	✓ Enacted	Aug 2023	Regulates generative AI services in China; healthcare AI applications subject to safety review and content governance.	www.cac.gov.cn
Japan	Cabinet Office / METI	AI Business Operator Guidelines (Apr 2024, Voluntary)	🔄 In Progress	Apr 2024	Voluntary guidelines for AI developers and operators; health AI considerations included; risk management principles.	www.meti.go.jp
Canada	ISED	AIDA — Artificial Intelligence and Data Act (Bill C-27)	🔄 In Progress	2022–2025	Parliament dissolved Mar 2025; Bill C-27 status uncertain; high-impact AI provisions would have covered health AI systems.	www.parl.ca
Brazil	Senate / Presidency	PL 2.338/2023 Marco Legal da IA (Under Review)	🔄 In Progress	2023–2025	Comprehensive AI legislation under Senate review; explicitly classifies health AI as high-risk; accountability provisions.	www25.senado.leg.br
Singapore	IMDA / MDDI	National AI Strategy 2.0 (Dec 2023)	✓ Enacted	Dec 2023	Updated national AI strategy; health and biomedical AI as priority sectors; AI governance frameworks for healthcare.	www.smartnation.gov.sg
Uruguay	AGESIC	AI Ethics Framework (2019)	✓ Enacted	2019	Early AI ethics framework; principles for public sector AI including health applications; transparency and accountability.	www.gub.uy
Argentina	Government	Argentina AI Plan 2030	🔄 In Progress	2023	National AI development strategy with health AI components; ethical principles and innovation promotion.	www.argentina.gob.ar
Chile	Ministry of Science	National AI Policy (2020)	✓ Enacted	2020	National AI policy framework; health AI identified as strategic priority; ethical guidelines under development.	minciencia.gob.cl
India	NITI Aayog	National AI Strategy — Health AI Components	🔄 In Progress	2018–2023	National AI strategy with significant health AI focus; responsible AI principles; no binding health AI legislation yet.	www.niti.gov.in
Colombia	INVIMA (internal)	InvimAgil — Internal AI Use	🔄 In Progress	2024–2025	INVIMA using AI tools internally for regulatory efficiency (InvimAgil initiative); no cross-sector AI legislation enacted.	www.invima.gov.co
Indonesia / Philippines / Thailand / Vietnam / Peru / Costa Rica / Ecuador / Bolivia / Paraguay / Guatemala / Panama	Various	No Specific AI or SaMD Regulation	✗ None	—	These jurisdictions currently have no enacted cross-sector AI legislation or dedicated SaMD/AI medical device regulation. Some follow ASEAN or WHO guidance informally.	—

Country Coverage Summary — June 2026

Overview of all jurisdictions assessed in this report, categorised by regulatory track.

Countries WITH Medical Device AI Guidance

 Enacted	EU
 Enacted	USA
 Enacted	UK
 Enacted	Canada
 Enacted	Australia
 Enacted	South Korea
 Enacted	Japan
 Enacted	China
 Enacted	Singapore
 Enacted	Taiwan
 Enacted	Malaysia
 Enacted	Saudi Arabia
 Enacted	UAE
 Enacted	Israel
 Enacted	Brazil
 Enacted	Mexico
 In Progress	Colombia
 Enacted	Argentina
 Enacted	IMDRF
 Enacted	WHO

General AI Legislation / No MD-Specific Guidance

 Enacted	EU (General AI Act)
 In Progress	USA (Trump AI EO)
 In Progress	UK (White Paper)
 Enacted	China (Generative AI)
 In Progress	Japan (Voluntary Guidelines)
 In Progress	Canada (AIDA — Uncertain)
 In Progress	Brazil (Marco Legal)
 Enacted	Singapore (NAS 2.0)
 Enacted	Uruguay
 In Progress	Argentina (AI Plan 2030)
 Enacted	Chile
 In Progress	India
 None	Indonesia
 None	Philippines
 None	Thailand
 None	Vietnam
 None	Peru
 None	Costa Rica
 None	Ecuador
 None	Bolivia
 None	Paraguay
 None	Guatemala
 None	Panama

Data Currency: This report reflects regulatory status as of **June 2026**. The AI regulatory landscape is evolving rapidly — new guidance documents, legislative amendments, and international harmonisation initiatives are expected throughout 2026 and beyond. Always verify current requirements through official regulatory authority sources or the RegDesk Platform before making regulatory decisions.

Abbreviations: MD = Medical Device; SaMD = Software as a Medical Device; AI/ML = Artificial Intelligence / Machine Learning; IMDRF = International Medical Device Regulators Forum; WHO = World Health Organization; GMLP = Good Machine Learning Practice; PCCP = Predetermined Change Control Plan.