

DOI: 10.5281/zenodo.12426901

# REGULATORY HARMONIZATION FRAMEWORK OF ARTIFICIAL INTELLIGENCE-BASED MEDICAL DEVICES: A SYSTEMATIC CROSS-COUNTRIES COMPARATIVE ANALYSIS, MATURITY CLASSIFICATION AND STRATEGIC ROADMAP

Shivali Rahi<sup>1</sup>, P.S Chandranand<sup>2</sup>, Arpana Rana<sup>3</sup>, Viney Lather<sup>4\*</sup>

<sup>1</sup>Amity Institute of Pharmacy, Amity University Uttar Pradesh, Noida-201313, India, Email id: shivalirahi@gmail.com, Orcid: <https://orcid.org/0000-0001-9784-3984>

<sup>2</sup>IQzyme Medtech Pvt Ltd, Kochi, Kerala- 682021, India; Global consultant, WHO prequalification of in-vitro diagnostics, India, Email id: drchandranand@iqzyme.com, Orcid: <https://orcid.org/0000-0002-7801-6032>

<sup>3</sup>Advanced Institute of Pharmacy, Palwal, Haryana- 121105, India, Email id: ranaarpana11@gmail.com, Orcid: <https://orcid.org/0000-0002-3864-9089>

<sup>4\*</sup>Amity Institute of Pharmacy, Amity University Uttar Pradesh, Noida-201313, India, Email id: vlather@amity.edu, Orcid: <https://orcid.org/0000-0002-7323-3142>

Received: 03/10/2025

Accepted: 13/01/2026

Corresponding Author: Viney Lather  
(vlather@amity.edu)

## ABSTRACT

*The rapid integration of artificial intelligence into medical devices is transforming clinical diagnostics, patient monitoring, and therapeutic decision-making globally. Despite this proliferation, regulatory framework governing AI-based medical devices remains systemically fragmented. This generates substantive patient safety risks, impeding equitable technology access and creating unsustainable compliance burdens for global manufacturers. To conduct a systematic, six-dimensional comparative assessment of AI-based medical device regulatory frameworks across nine regulatory authorities and synthesize findings into a novel, theoretically grounded seven-step strategic harmonization roadmap aligned with IMDRF, ISO, IEC, GMLP, and WHO AI ethics principles. Thematic content analysis of regulatory documents (2015– early 2026) was conducted using NVivo 14 through open and axial coding. Inter-rater reliability was established via independent dual coding (Cohen's Kappa  $\kappa = 0.865$ , 95% CI: 0.79–0.93,  $p < 0.001$ ). A five-point ordinal maturity scoring rubric was applied across six regulatory dimensions. The roadmap was theoretically grounded in Kingdon's Multiple Streams Framework and Rogers' Diffusion of Innovations theory. A novel four-tier regulatory maturity classification was empirically derived as Tier I: USA, EU, Japan; Tier II: UK, Canada, China; Tier III: Australia, Singapore; Tier IV: India. Adaptive algorithm system, patient-centric obligations, cybersecurity provisions, and mutual recognition infrastructure were identified as cross-cutting structural gaps. The seven-step roadmap addresses these through common definitional frameworks, risk-aligned approval pathways, regulatory sandboxes, mutual recognition agreements, real-world evidence integration, cybersecurity embedding and permanent global coordination. Four independent scholarly contributions are delivered: a nine-countries*

*regulatory authorities' comparative matrix, a validated maturity scoring system ( $\kappa = 0.865$ ), an original four-tier taxonomic classification and a theoretically anchored seven-step harmonization roadmap. All these collectively provide the most comprehensive operational foundation currently available for globally coherent, patient-safe AI- based medical device regulations.*

---

**KEYWORDS:** AI-based medical devices; Regulatory harmonization; Software as a Medical Device (SaMD); Adaptive algorithms; Risk-based classification; Cybersecurity; Comparative policy analysis; IMDRF; Predetermined Change Control Plans.

---

## Introduction

Artificial intelligence (AI) technologies are fundamentally transforming medical device innovation, enabling advanced diagnostic capabilities, personalized therapeutic interventions, and real-time clinical decision support systems.(1,2) Unlike conventional medical devices characterized by static functionality and predictable performance profiles, AI-based medical devices exhibit dynamic, data-driven behaviors that evolve through continuous learning algorithms.(3) This fundamental distinction exposes a critical regulatory mismatch frameworks that are designed for static devices which are inherently unable to accommodate the real-time performance monitoring, continuous validation and adaptive risk assessment that AI-based medical technologies demand throughout their operational lifecycle.(4)

The regulatory challenge is compounded by the fundamentally cross-jurisdictional nature of AI medical device development.(5) AI-enabled diagnostic algorithms, clinical decision support systems and adaptive monitoring platforms are designed for global markets. However, they face a complex challenge that every country has its own unique set of regulations with distinct definitional boundaries, risk classification architectures, and approval requirements.(6) This fragmentation imposes unsustainable compliance burdens on manufacturers, creates unpredictable approval timelines, and generates inequitable patient access to AI-driven healthcare technologies across economic and regulatory contexts. (7)

Contemporary regulatory developments reflect attempts to address these challenges. The European Union's Medical Device Regulation (MDR) and *In-Vitro* Diagnostic Regulation (IVDR), alongside the U.S. Food and Drug Administration's (FDA) is actively developing new monitoring approaches specifically for AI-based medical technologies. Companies must now provide evidence demonstrating that their AI algorithms produce consistent, reliable results every time.(8,9) The FDA's Good Machine Learning Practice (GMLP) guidelines (10) and Predetermined Change Control Plans (PCCPs) (11) provide structured approaches for managing algorithm updates and post-market modifications. Concurrently, the proposed EU AI Act introduces conformity assessments and high-risk classifications for AI-enabled software, emphasizing safety accountability and data integrity.(12) The more directly applicable standards for AI in medical devices include ISO/IEC 81001-1 (health software), ISO/IEC 22989 (AI concepts and

terminology), IEC 62304 (medical device software lifecycle) and ISO 14971 (risk management) advocate harmonized terminology, risk management protocols, and cybersecurity safeguards.(13,14) Nevertheless, these frameworks confined to national or regional levels, underscoring the need for harmonized and globally aligned regulatory pathways.(6,15)

The increasing prevalence and complexity of AI-based medical devices necessitate harmonized regulatory approaches to ensure safety, efficacy, and ethical deployment.(16,17) The alignment of disparate national regulatory requirements and standards toward uniform global approaches as regulatory harmonization represents a collaborative effort among international organizations, regulatory authorities and industry stakeholders. This convergence aims to enhance patient safety, reduce regulatory redundancy and facilitate global trade in healthcare technologies.(18) Numerous regulatory bodies have implemented medical device regulations but the absence of global harmonization creates significant regulatory hurdles that impede timely access to high-quality medical devices.(19) Current regulatory frameworks predominantly focus on Software as a Medical Device (SaMD), yet these provisions may prove insufficient for AI technologies capable of autonomous operation and continuous learning.(20,21)

The existing medical device regulatory frameworks provide foundational structures but they weren't designed for AI. The rapidly evolving landscape of AI-enabled medical device software systems necessitates tailored regulatory approaches.(22) The absence of precise AI-specific regulatory requirements generates sector-wide ambiguity, increases interpretive uncertainty regarding existing mandates. This creates unclear expectations from regulatory authorities, thereby amplifying compliance challenges and submission preparation complexities.(23) Consequently, AI-based medical device development requires comprehensive lifecycle approaches encompassing design, development, verification, validation, deployment, operation and continuous monitoring to streamline compliance efforts while ensuring safety, security, clinical effectiveness and timely market authorization.(24,25)

The regulatory landscape for AI-based medical devices encompasses complex technical, legislative and normative considerations. [10] This study aims to: (i) conduct a rigorous, six-dimensional

comparative assessment of AI-based medical device regulatory frameworks across nine carefully selected regulatory authorities; (ii) identify structural and operational gaps impeding regulatory harmonization, patient safety, and equitable technology access; (iii) synthesize findings into a theoretically grounded, operationally actionable seven-step strategic roadmap for global regulatory harmonization. The study encompasses AI-based medical devices as defined by IMDRF SaMD classification principles, evaluated through analysis of regulatory documents, guidelines and technical standards published during 2015– early 2026.

Despite growing scholarly and regulatory attention to this domain, a critical gap persists in the literature that no prior study has conducted a systematic, multi-regional comparative analysis of AI-based medical device regulatory frameworks across a representative cross-section of global economies and simultaneously proposed an operationally specific, theoretically grounded harmonization roadmap.(26,27) This study addresses that gap directly through rigorous cross-country comparative assessment and synthesis of strategic roadmap for harmonization of AI-based medical devices.

## 2. Literature Review and Gap identification

A structured review of the existing literature was conducted to systematically map the scholarly and regulatory landscape governing AI-based medical device governance, identify specific gaps that this study addresses, and precisely situate the novel contributions of this work within the existing knowledge base. The review encompassed peer-reviewed publications, regulatory agency guidance documents, and international standards body publications indexed in Scopus, PubMed, Web of Science, and Embase between 2015 and early 2026, using search terms including 'AI medical device regulation', 'SaMD regulatory framework', 'machine learning medical device governance', 'regulatory

harmonization digital health', and 'AI healthcare policy comparison'.

### 2.1 State of Knowledge

The existing literature organizes into three principal streams, each making important but partial contributions. The first stream comprises agency-specific regulatory analyses examining individual regulatory bodies primarily FDA, EU MDR/ AI Act, and to a lesser extent PMDA and NMPA with particular attention to approval pathway evolution, SaMD classification, and post-market surveillance.(28–30) While providing granular insight into specific regulatory framework, these analyses are inherently bounded by their single-country scope and cannot enable cross-country comparative assessment or harmonization strategy development.(31)

The second stream addresses the ethical and philosophical dimensions of AI governance in healthcare, engaging with principles of transparency, accountability, fairness and human monitoring.(32,33) Although instrumental in establishing normative foundations of responsible AI deployment, this literature consistently falls short of translating ethical principles into operationally implementable regulatory requirements.(34,35)

The third stream focuses on regulatory gap analysis and advocacy for harmonization, identifying key deficiencies in existing frameworks and emphasizing the need for stronger international coordination. (26,36) However, even the most substantial contributions within this stream remain limited in terms of multi-country scope, methodological rigor, and operational specificity, thereby lacking the systematic cross-country analysis and actionable roadmap required by the field. Table 1 presents a structured synthesis of key prior studies, their contributions and the specific gaps filled by our study.

Source	Focus Area	Contribution	Gap Not Addressed (filled by this study)
Muehlematter et al. (2021) (30)	FDA & EMA approval trends 2015–2021	Single-time approval trajectory analysis	<ul style="list-style-type: none"> <li>• No post-market AI governance.</li> <li>• No harmonization strategy.</li> <li>• Excludes emerging-market countries.</li> </ul>
Benjamens et al. (2020) (37)	FDA-cleared AI/ML device performance benchmarking	Device performance mapping	<ul style="list-style-type: none"> <li>• No regulatory framework comparison.</li> <li>• No cross-country policy analysis.</li> </ul>

Gerke, Minssen & Cohen (2020) (38)	Ethical and legal challenges of AI-driven healthcare	Conceptual ethics and liability mapping	<ul style="list-style-type: none"> <li>• No operational regulatory pathway analysis.</li> <li>• No harmonized roadmap.</li> </ul>
Char, Shah & Magnus (2018) (39)	Ethical implementation of ML in clinical settings	Bioethics and clinical governance principles	<ul style="list-style-type: none"> <li>• No regulatory framework evaluation.</li> <li>• No policy harmonization strategy.</li> </ul>
Finch & Butt (2025) (40)	Regulatory gaps in clinical AI governance	Legislative void identification	<ul style="list-style-type: none"> <li>• Primarily EU/US binary comparison.</li> <li>• No systematic nine-countries scope.</li> <li>• No actionable roadmap.</li> </ul>
WHO (2021) (41)	Global ethics framework for AI in health	Normative ethical guidance document	<ul style="list-style-type: none"> <li>• Non-binding.</li> <li>• No risk-based regulatory classification.</li> <li>• No country-specific gap analysis.</li> </ul>
IMDRF (2021) (42)	AI/ML SaMD classification and definitional scaffolding	Classification framework foundation	<ul style="list-style-type: none"> <li>• Framework-only</li> <li>• No approval pathway harmonization.</li> <li>• No cybersecurity or lifecycle specifics.</li> </ul>
Our study	Nine-countries systematic regulatory comparison, six-dimensional thematic analysis, inter-rater validated scoring	Comparative maturity scoring + Tier I-IV classification + theoretically grounded seven-step harmonization roadmap	Addresses all identified gaps: multi-country scope, AI-specific dimensions, validated scoring system, theoretical grounding, inter-rater reliability, operational roadmap with timelines.

**Table 1. Structured literature gap matrix demonstrating how prior studies collectively leave a critical gap that this study addresses.**

The gap analysis confirms that no prior publication has simultaneously delivered a nine-countries systematic comparison, a validated quantitative maturity scoring methodology, an original regulatory maturity tier taxonomy and a theoretically grounded, implementation-sequenced harmonization roadmap.

## 2.2 Theoretical Grounding of the Harmonization Roadmap

A key limitation of existing harmonization literature is the lack of a robust theoretical foundation underpinning proposed sequences of regulatory reform. In the absence of a strong theoretical foundation, proposed roadmaps lack the conceptual framework required to justify their design and to anticipate implementation dynamics. This study addresses this limitation by grounding the seven-step roadmap in two complementary, well-established frameworks.

Kingdon's Multiple Streams Framework (MSF) is adopted as the principal macro-level analytical framework.<sup>(43)</sup> Multiple Streams Framework asserts that successful policy change is achieved through the alignment of three distinct and independent streams i.e a problem stream (recognition of the policy problem), a policy stream (development of viable solutions), and a politics stream (political will and institutional capacity for change).<sup>(44)</sup> In the context of AI medical device harmonization, MSF elucidates why prior efforts have stalled. The problem stream is well defined. However, alignment has not been achieved. This is due to gaps in the policy stream, particularly the absence of a clear and implementable roadmap. Additionally, the politics stream is weak due to lack of a sustained coordination mechanism. The seven-step roadmap operationalizes the policy stream (Steps 1–6) and institutionalizes the political stream (Step 7),

enabling the three streams to converge into sustainable harmonization policy change.

Rogers' Diffusion of Innovations Theory provides the micro-level implementation rationale for the roadmap's modular framework. Rogers' theory predicts that policy innovations are adopted progressively across populations characterized by different readiness levels, from early adopters (Tier I countries) through early majority (Tier II), late majority (Tier III), to laggards (Tier IV).<sup>(45)</sup> The roadmap's modular design enable countries to enter at the step appropriate to their regulatory maturity ensuring harmonization is designed for realistic adoption dynamics rather than aspirational simultaneous convergence.

### 3. Methodology

#### 3.1 Research Design

This study uses a qualitative, exploratory research design based on interpretivist policy analysis. A qualitative approach was chosen to better understand complex and diverse policy frameworks, institutional strategies and regulatory documents that cannot be easily analyzed and regulatory documents that are not readily amenable to quantitative reduction. The methodological framework integrates thematic content analysis, comparative policy analysis, and strategic gap assessment within a structured analytical matrix, enabling within-country (vertical) and cross-country (horizontal) comparative assessments across all six regulatory dimensions.

#### 3.2 Data Collection and Country Selection

Systematic identification and retrieval of 185 regulatory documents, technical white papers, guidance publications, and international standards published between 2015 and early 2026 was conducted. Sources were drawn from nine national regulatory bodies: FDA (USA), EMA (EU), PMDA (Japan), NMPA (China), MHRA (UK), Health Canada, TGA (Australia), HSA (Singapore), and CDSCO (India), supplemented by documents from IMDRF, WHO, ISO, IEC, and IEEE. Country selection criteria encompassed regulatory diversity, Oxford Insights Government AI Readiness Index scores, GDP and medical device market size,

ensuring both horizontal (high-to-lower-income) and vertical (policy maturity) comparative range.

#### 3.3 Analytical Framework

Thematic content analysis was conducted using NVivo 14 through two stages: open coding, in which codes were generated inductively without predefined categories, permitting themes to emerge organically; and axial coding, categorizing codes into six predefined regulatory dimensions: device classification systems, approval and licensing pathways, cybersecurity and software safety, patient-centric and ethical provisions, AI-specific technical standards adoption, and adaptive algorithm and continuous learning monitoring. A five-point ordinal maturity scoring system was applied to each dimension for each country. A four-phase comparative policy framework was subsequently applied which include mapping, gap identification, benchmarking and roadmap development.

#### 3.4 Inter-Rater Reliability: Establishing Methodological Credibility

The validity of this study's comparative findings and the evidence supporting the seven-step harmonization roadmap depends on an important methodological condition that is often overlooked in descriptive policy research. The judgments encoded in the maturity scoring system are not idiosyncratic products of a single analyst's interpretive framework. Instead, it should produce stable and consistent results. This means that any competent regulatory science researcher, using the same scoring on the same documents, should arrive at similar conclusions. The methodological response to this challenge is well-established in qualitative research: independent dual coding with formal inter-rater reliability assessment using Cohen's Kappa statistic, which quantifies the degree of agreement between coders beyond what chance alone would produce. The results are reported in Table 2 confirm that the maturity scoring system meets the reliability standards required for its use as a validated original methodological contribution to the comparative regulatory science literature.

Regulatory Dimension	Cohen's Kappa ( $\kappa$ )	Agreement Level	95% CI	Reconciliation Needed
Classification System	0.87	Substantial-Almost Perfect	0.79-0.94	No
Regulatory Guidance	0.84	Substantial	0.76-0.91	No

<b>Approval Process</b>	0.89	Almost Perfect	0.82–0.95	No
<b>Cybersecurity Regulations</b>	0.91	Almost Perfect	0.85–0.96	No
<b>Patient-Centric Provisions</b>	0.82	Substantial	0.74–0.90	No
<b>AI-Specific Standards</b>	0.86	Substantial-Almost Perfect	0.78–0.93	No
<b>Overall Mean (<math>\kappa</math>)</b>	0.865	Almost Perfect	0.79–0.93	—

**Table 2. Inter-rater reliability results for independent dual coding across six regulatory dimensions**

The mean Cohen's Kappa of 0.865 (95% CI: 0.79–0.93,  $p < 0.001$ ) substantially exceeds the 0.70 threshold conventionally accepted in qualitative policy research, confirming near-perfect inter-rater agreement across all dimensions. In all instances of initial disagreement (affecting fewer than 14% of coded items), consensus was reached through structured discussion referencing the scoring rubric definitions. These results confirm the reliability and reproducibility of the maturity scoring methodology as a validated original contribution to regulatory science methodology.

### 3.5 Limitations

This study acknowledges four principal methodological constraints that circumscribe the generalizability of its findings and define a clear future research agenda.

First, the analysis is bounded by publicly accessible regulatory documents, excluding confidential internal agency guidance, restricted draft consultations, and informal regulatory practices. This is particularly relevant for countries such as China and India, where unofficial regulatory communications can strongly influence decisions, even if they are not formally documented.

Second, no primary qualitative data collection through stakeholder interviews or expert focus groups was conducted due to resource constraints. The absence of direct regulatory official perspectives limits the capacity to account for political, institutional and capacity factors shaping regulatory maturity. This limitation is partially mitigated through systematic integration of formal consultation reports, regulatory white papers and published stakeholder submissions.

Third, the five-point maturity scoring system, although validated through inter-rater reliability assessment, still requires some judgment when deciding between closely related score levels. The systems basic assumptions may not hold uniformly across dimensions with non-linear development pathways, such as cybersecurity,

where technological threat landscapes evolve discontinuously rather than in ordinal progress. Fourth, the study covers a time period of rapid regulatory evolution. Several regulatory bodies such as the EU (AI Act finalization), UK (SaMD Change Programme) and Canada (AIDA) were engaged in active regulatory development at the time of data collection. The regulatory status of some dimensions may have evolved since coding was completed. The roadmap's modular and iterative framework is designed to accommodate this dynamism, but the gap analysis findings should be interpreted as a temporal snapshot rather than a static characterization.

The period between data collection and publication witnessed a concentration of significant regulatory developments that affect the manuscript's characterization of several countries. These include: the MDCG 2025-6/AIB 2025-1 joint guidance formalizing the 'Medical Device Artificial Intelligence' designation and dual MDR/IVDR-AI Act compliance obligations (EU, June 2025). The MHRA AI Airlock Phase 1 completion and Phase 2 launch establishing the world's first AI medical device regulatory sandbox (UK, March 2025 onward). Singapore HSA's Revision 4 of GL-04 explicitly governing ML-enabled medical devices with continuous learning and change management requirements (December 2025). India's CDSCO draft guidance on AI-based medical devices representing the first substantive AI-specific regulatory signal from a Tier IV country (October 2025). Each of these developments has been acknowledged and incorporated into the manuscript's narrative discussion where feasible.

### 4. Results

The regulatory landscape for AI-based medical devices exhibits pronounced heterogeneity across all nine examined regulatory authorities. The following sections present findings organized by analytical component, culminating in the strategic harmonization roadmap.

#### 4.1 Novel Four-Tier Regulatory Maturity Classification

A novel four-tier classification of global AI-based medical device regulatory readiness is produced by the cross-country analysis. The inter-rater coding

process has verified that the classification accurately depicts genuine qualitative discontinuities in the regulatory framework between tier groupings.(46) The maturity scoring matrix is comprehensively illustrated in Table 3.

Country	Classification	Regulatory Guidance	Approval	Cybersecurity	Patient-Centricity	AI Standards	Maturity Tier
USA	5	5	5	5	5	5	Tier I
EU	5	4	4	4	4	4	Tier I
Japan	5	4	4	4	4	4	Tier I
China	4	3	4	5	3	3	Tier II
UK	4	4	4	4	4	3	Tier II
Canada	3	4	3	4	3	3	Tier II
Australia	3	3	3	3	2	3	Tier III
Singapore	3	2	3	3	2	3	Tier III
India	2	1	2	1	1	1	Tier IV

**Table 3. Regulatory maturity scoring matrix across nine countries and six dimensions. Scores: 1 (no policy/regulation exists) through 5 (comprehensive, adaptive, AI-specific framework operational).**

##### 4.1.1 Tier I - Advanced Jurisdictions (Mean $\geq 4.5$ ): USA, EU, Japan

The United States FDA continues to lead global AI medical device governance through a series of landmark regulatory developments. In December 2024, FDA issued final guidance on PCCPs for AI-enabled device software functions, confirming the core PCCP structure encompassing Description of Modifications, Modification Protocol, and Impact Assessment.(11) This was superseded in August 2025 by a more comprehensive final PCCP guidance representing the current authoritative framework.(11) In January 2025, FDA published draft guidance on AI-enabled Device Software Functions lifecycle management, a Total Product Lifecycle-based framework requiring model description, data lineage, bias analysis and post-market performance monitoring in submissions.(28,47) Complementing these developments, FDA published Guiding Principles on Transparency for ML-Enabled Medical Devices in June 2024. The Quality Management System Regulation (21 CFR 820) came into force on February 2, 2026. This regulation aligns U.S. quality monitoring with ISO 13485:2016. It directly impacts AI device change control under Predetermined Change Control Plans (PCCPs).(48) As of 2026, over 1,000 AI/ML-enabled devices have received

clearance or approval from the USFDA with radiology continuing to dominate at approximately 70-75%.(49) The uptake of Predetermined Change Control Plans (PCCPs) remains limited, accounting for less than one-fifth of recent clearances, indicating that adaptive approval approaches have yet to gain widespread acceptance.(50)

The EU's framework demonstrates exceptional depth through the MDR, IVDR, and AI Act's four-tier risk classification.(51-53) In June 2025, the MDCG and the Joint AI Board published MDCG 2025-6/AIB 2025-1 and introduced the term "Medical Device Artificial Intelligence (MDAI)" and clarified expectations for manufacturers. From 2026 onwards, companies developing AI-enabled medical devices must meet both MDR/IVDR requirements and the AI Act at the same time, including rules on data governance, transparency, human monitoring and technical documentation. (54,55) Additionally, proposed legislation in late 2025 aims to simplify MDR/IVDR processes and address ongoing capacity issues with Notified Bodies that have previously slowed down regulatory processes. (56)

Pharmaceuticals and Medical Devices Agency of Japan adopt a lifecycle-based regulatory model that allows conditional approvals and effectively integrates real-world evidence, making it particularly well suited for adaptive AI. In addition,

its expanded sandbox program supports early-stage testing of AI/ML technologies.(57-59)

#### **4.1.2 Tier II - Developing Jurisdictions (Mean 3.3-4.0): UK, Canada, China**

The UK MHRA's Software and AI as a Medical Device Change Programme signals progressive development with adaptive AI regulation concepts.(60,61) The MHRA AI Airlock was the world's first regulatory sandbox specifically for AI as a medical device completed its pilot phase in March 2025 and launched Phase 2 with focus on risk classification, change management planning, and bias/fairness metrics.(62,63) In July 2025, the MHRA published an international reliance scheme enabling devices already cleared by FDA, Health Canada, or TGA to gain UK market access with significantly reduced evidence requirements, reflecting a deliberate shift toward regulatory convergence. The December 2024 legislative roadmap established new pre-market regulations expected in 2026, a revised SaMD classification system upgrading most SaMD from Class I to Class IIa, and extended CE mark recognition to June 2030, providing manufacturers with near-term regulatory certainty.(64) The trilaterally developed MHRA-FDA-Health Canada GMLP principles which are comprising of ten core principles and five PCCP-specific principles that further demonstrate the UK's active engagement in international AI medical device governance harmonization.(10)

Canada's broader ambitions for AI regulation have faced setbacks. The Artificial Intelligence and Data Act (AIDA, Bill C-27) which was introduced in June 2022, lapsed on January 6, 2025 following parliamentary prorogation and the federal government has confirmed it will not be revived.(65,66) As of now, no successor bill has been tabled, leaving Canada without binding national AI-specific legislation.(67,68) Current AI governance for medical devices relies on existing SaMD guidance, Personal Information Protection and Electronic Documents Act (PIPEDA) privacy provisions, and a voluntary Code of Conduct on Responsible Development of Generative AI Systems (2023), none of which constitute binding AI-specific regulatory obligations.(69)

China's NMPA follows a centralized, security-focused regulatory trajectory, with draft guidance on AI-based SaMD emphasizing algorithm validation, software update governance, and data localization requirements; however, adapting this framework to accommodate continuously learning systems in

clinical settings remains a significant unresolved challenge. (70-72)

#### **4.1.3 Tier III - Transitional Jurisdictions (Mean 2.3-3.0): Australia, Singapore**

Australia's TGA mandates ARTG registration for AI-enabled devices and has established voluntary AI Ethics Principles.(73,74) TGA published updated guidance in early 2026 clarifying when AI qualifies as a medical device, specifying compliance requirements with IEC 62304 and ISO 14971.(74)

HSA published Revision 4 of GL-04 (Regulatory Guidelines for Software Medical Devices-A Lifecycle Approach) in December 2025, explicitly covering machine learning-enabled medical devices (MLMDs) with specific requirements for continuous learning controls, post-market performance monitoring, and structured change management.(72) In 2024, HSA introduced the Change Management Program (CMP), a Pre-Specified Change (PSC) pathway analogous to FDA PCCPs, specifically covering ML-enabled SaMD. This was revised in early 2025 based on industry feedback. In May-June 2025, HSA consulted on a regulatory sandbox for AI-SaMD developed by public healthcare institutions (Class A and B AI-SaMD), with findings published in February 2026 confirming sandbox parameters. In July 2025, HSA updated its SaMD and CDSS classification guidelines (GN-13 revision), aligning with IMDRF terminology and adding AI-specific classification criteria.(78) Cybersecurity guidance for SaMD is explicitly addressed within the updated GL-04 framework. Singapore and Malaysia formalized a regulatory reliance pathway in 2025/2026.(79)

#### **4.1.4 Tier IV - Nascent Jurisdiction (Mean 1.3): India**

India's CDSCO highlights a major area for development. AI-based devices are currently regulated under the Medical Devices Rules (2017) (80) without any AI-specific framework. On October 21, 2025, CDSCO released its Draft Guidance Document on Medical Device Software, a 76-page document that fundamentally changes India's regulatory landscape for AI/SaMD.(81,82) A four-class risk-based classification system (Class A to D) has been introduced, aligned with global practices, based on significance of information and severity of healthcare situation. The draft explicitly covers AI/ML-based medical devices, cloud-hosted software, and machine learning algorithms. Quality Management System requirements aligned with ISO 13485 are mandated. An Algorithm Change Protocol

(ACP) is introduced for managing AI/ML updates, functionally analogous to FDA PCCPs. Cybersecurity requirements are addressed within the lifecycle framework. Post-market surveillance obligations are explicitly included for software-based devices. Class C and D SaMD (including high-risk AI tools) fall under CDSCO's Central Licensing Authority. While implementation remains pending, the existence of a structured draft, explicitly addressing AI/ML, risk-based classification, cybersecurity, and an ACP, represents material regulatory progression that affects scores on at least four of the six dimensions. (83,84)

#### 4.2 Paradigm Divergence: Traditional vs. AI Medical Device Regulation

The traditional medical device regulations have historically provided robust frameworks for evaluating the safety and effectiveness of static devices. AI-based medical technologies present unique challenges that extend beyond the scope of

existing models. AI-based medical devices are adapting over time which necessitates continuous validation, post-market performance monitoring, and cybersecurity management. A prerequisite for effective harmonization is recognition of the fundamental paradigmatic divergence between static medical device regulation and dynamic AI governance requirements.(85) Consequently, the harmonization of regulatory frameworks must focus on integrating the strengths of traditional systems with AI-specific considerations, ensuring a cohesive, potentially productive regulatory environment. These efforts indicate a global trend toward evolving conventional regulatory tools into hybrid models capable of addressing the continuous-learning nature of artificial intelligence. Table 4 maps these contrasts across nine critical dimensions and provides the conceptual foundation by justifying why traditional static medical device approval frameworks are categorically inadequate for governing continuously learning AI systems.

Dimension	Traditional Medical Devices	AI-Based Medical Devices
<b>Device Behavior</b>	Static-fixed, deterministic functionality; predictable outputs throughout operational lifespan	Dynamic-probabilistic, continuously learning; outputs may evolve substantially post-deployment based on new data streams.
<b>Regulatory Focus</b>	Point-in-time safety and effectiveness evaluation at initial approval only	Ongoing lifecycle management: pre-market, post-market, and real-time continuous monitoring phases.
<b>Approval Process</b>	Single-instance regulatory clearance (510(k), CE Mark, PMA) with discrete change notifications	Iterative adaptive mechanisms: PCCPs, conditional approvals, sandbox-based evidence accumulation.
<b>Classification System</b>	Risk determined by device function as fixed and declared at time of submission	Risk profile evolves dynamically with algorithm updates, new training data, or novel deployment contexts.
<b>Post-Market Surveillance</b>	Routine monitoring for hardware malfunction and adverse events; periodic safety reviews	Continuous algorithm validation, model drift detection, RWE collection, retraining oversight, version control.
<b>Cybersecurity</b>	Basic hardware/software protections; limited connectivity; minimal ongoing obligations	Critical and multidimensional: cloud integration, adversarial attacks, AI model exploitation, continuous patch management.
<b>Patient-Centric Focus</b>	General user safety, usability standards, labelling compliance	Algorithmic explainability, bias auditing, informed consent for AI-assisted decisions, health equity provisions.
<b>Standards</b>	ISO 13485, IEC 60601, ISO 14971	ISO/IEC 23894:2023 (Information technology, Artificial intelligence), ISO/IEC 81001-1 (health software), ISO/IEC 22989 (AI concepts and

terminology), IEC 62304 (medical device software lifecycle), and ISO 14971 (risk management), GMLP, IMDRF SaMD principles.

<b>Regulatory Adaptability</b>	Limited: approval essentially definitive; modifications trigger discrete notifications	Requires dynamic oversight, predefined change protocols, responsive reclassification processes.
--------------------------------	--	---

**Table 4. Comparative analysis of traditional versus AI-based medical device regulatory requirements across nine critical governance dimensions, illustrating the paradigm shift necessitating novel regulatory approaches.**

The comparison table illustrates how regulatory expectations for AI-based devices diverge from traditional norms, highlighting areas where requirements are either more stringent or still under development.

**4.3 Structural and Operational Gap Analysis**

Regulatory maturity scores reveal what frameworks possess while gap analysis reveals what they lack. The gaps have greater consequence for patient safety, innovation equity, and global market coherence.(86) A regulatory system may score adequately on classification and approval pathways, yet still be unprepared to manage continuously learning algorithms, monitor performance changes

after deployment, or address cross-border algorithmic bias.(87) This asymmetry between surface-level regulatory presence and deeper operational readiness is precisely what the following analysis is designed to expose. Using the inter-rater validated six-dimensional coding framework applied across all nine countries, the gap analysis systematically identifies where regulatory infrastructure is not merely underdeveloped but structurally misaligned with the demands of adaptive AI governance. Table 5 presents a tiered synthesis of critical structural and operational gaps identified through inter-rater validated thematic content analysis, organized by the novel four-tier classification.

Tier	Countries	Key Regulatory Strengths	Critical Gaps Requiring Harmonization
<b>Tier I</b>	USA, EU, Japan	<ul style="list-style-type: none"> <li>Adaptive approval pathways (PCCPs).</li> <li>Mature lifecycle monitoring.</li> <li>Strong cybersecurity frameworks.</li> <li>AI-specific standards (IMDRF, GMLP, ISO).</li> <li>Emerging patient-centric obligations.</li> </ul>	<ul style="list-style-type: none"> <li>Formalization of algorithmic explainability mandates.</li> <li>Mutual recognition infrastructure for AI-specific technical assessments.</li> <li>Real-time adaptive oversight for generative AI systems in clinical use.</li> </ul>
<b>Tier II</b>	UK, Canada, China	<ul style="list-style-type: none"> <li>Structured SaMD classification.</li> <li>Lifecycle management frameworks.</li> <li>Emerging AI-specific guidance.</li> <li>Cybersecurity alignment with ISO 27001 and PIPL.</li> </ul>	<ul style="list-style-type: none"> <li>Comprehensive patient-centricity obligations.</li> <li>Adaptive algorithm approval mechanisms.</li> <li>Bilateral MRA infrastructure specifically for AI conformity assessments.</li> </ul>
<b>Tier III</b>	Australia, Singapore	<ul style="list-style-type: none"> <li>Risk-based SaMD classification.</li> <li>AI ethics principles (voluntary).</li> <li>Basic cybersecurity provisions aligned with general IT standards.</li> </ul>	<ul style="list-style-type: none"> <li>AI-specific classification systems.</li> <li>Dynamic approval mechanisms.</li> <li>Post-market AI-specific surveillance protocols.</li> <li>Algorithmic bias and explainability regulatory frameworks.</li> </ul>
<b>Tier IV</b>	India	<ul style="list-style-type: none"> <li>Broad medical device regulatory framework operational.</li> </ul>	<ul style="list-style-type: none"> <li>AI-specific classification</li> <li>Cybersecurity mandates for medical AI</li> </ul>

- SaMD rules proposed but not fully implemented.
- Continuous learning oversight
- Patient-centric AI provisions
- Adoption of international technical standards.

**Table 5. Tiered synthesis of structural and operational regulatory gaps by country tier. Gaps represent deficiencies identified through inter-rater validated thematic content analysis ( $\kappa = 0.865$ ) and comparative policy benchmarking**

From the analysis, it was found that four cross-cutting gaps of particular policy significance are emerged. First, adaptive algorithm governance is the most pervasive gap. Even Tier I countries lack comprehensive provisions for continuous post-deployment performance monitoring and regulatory response to algorithm drift at scale. Second, patient-centric obligations such as explainability, bias auditing, informed consent for AI-assisted decisions are nascent across all tiers. Third, cybersecurity provisions remain inadequate for networked, cloud-integrated AI medical systems across Tier II-IV countries. Fourth, mutual recognition infrastructure for AI-specific technical assessments is largely absent globally, forcing duplicative country-specific approvals that substantially extend time-to-market and increase development costs.

#### 4.4 The Seven-Step Strategic Harmonization Roadmap

By combining the comparative assessment, gap analysis and theoretical frameworks, this study proposes a novel seven-step roadmap whose sequencing is explicitly theoretically justified. The first two steps build the foundation of the policy stream based on Kingdon's Multiple Streams Framework (MSF). Steps 3-4 focus on strengthening institutional capacity and developing systems for regulatory reliance. Steps 5-6 incorporate essential technical and ethical elements into the framework. Finally, step 7 establishes a permanent coordination mechanism that enables the problem, policy, and politics streams to come together, supporting long-term and sustainable harmonization. The roadmap's modularity reflects Rogers' diffusion architecture for realistic adoption across Tier I-IV contexts. Table 6 presents the comprehensive roadmap for harmonization.

Step	Component	Strategic Action	Priority Countries	Timeline
1	Establishing Common Definitions and Scope	<ul style="list-style-type: none"> <li>• Develop globally agreed terminology for AI/ML-based medical devices, SaMD, adaptive algorithms and CDSS.</li> <li>• Align with ISO 22989, IMDRF SaMD principles, FDA AI/ML Action Plan.</li> <li>• Eliminate definitional fragmentation as a prerequisite for all subsequent harmonization steps.</li> </ul>	All countries	0-12 months
2	Aligning Risk-Based Classification and Approval Pathways	<ul style="list-style-type: none"> <li>• Harmonize dynamic risk frameworks integrating AI-specific factors: adaptivity, algorithm opacity, data drift.</li> <li>• Transition from static single-instance approval toward iterative mechanisms (PCCPs, conditional approvals).</li> <li>• Align cross-border approval criteria to enable regulatory reliance.</li> </ul>	All countries	6-18 months
3	Building Capacity via Regulatory Sandboxes	<ul style="list-style-type: none"> <li>• Establish controlled sandbox environments for real-world adaptive AI algorithm testing under regulatory supervision.</li> <li>• Bridge gap between policy alignment and operational readiness.</li> <li>• Enable local testing of IMDRF/FDA PCCP adaptations before full regulatory integration.</li> </ul>	India, Singapore, China, Australia (priority)	12-24 months
4	Promoting Mutual Recognition and	<ul style="list-style-type: none"> <li>• Develop bilateral and multilateral MRAs enabling cross-border acceptance of technical assessments, conformity evaluations and cybersecurity certifications.</li> <li>• Model on IMDRF MDSAP and ASEAN AMDD frameworks.</li> </ul>	Advanced and developing	18-30 months

Step	Component	Strategic Action	Priority Countries	Timeline
5	Reliance Agreements	<ul style="list-style-type: none"> <li>Reduce duplicative evaluation burden for global manufacturers.</li> </ul>	country pairs	
	Integrating Lifecycle Oversight and Real-World Evidence	<ul style="list-style-type: none"> <li>Establish harmonized standards for algorithm update tracking, model versioning, post-market surveillance protocols, audit logging and evidence-threshold-triggered regulatory review.</li> <li>Enable dynamic reclassification based on accumulated real-world performance data.</li> </ul>	All countries	18-36 months
6	Embedding Ethical, Cybersecurity, and Patient-Centric Provisions	<ul style="list-style-type: none"> <li>Mandate algorithmic explainability, representative training data requirements and bias auditing.</li> <li>Align with ISO 81001-1, FDA Premarket Cybersecurity Guidance.</li> <li>Embed equity, informed consent, and patient rights frameworks as binding regulatory obligations.</li> </ul>	All countries (concurrent with Steps 2-5)	Ongoing
7	Institutionalizing a Global Coordination Platform	<ul style="list-style-type: none"> <li>Establish a permanent international AI medical device governance body under WHO/IMDRF auspices.</li> <li>Maintain living repository of regulatory practices and AI risk reclassifications.</li> <li>Coordinate capacity-building, joint assessments and ongoing MRA negotiation and updates.</li> </ul>	Global- all countries	24-48 months

**Table 6. Seven-step strategic harmonization roadmap for AI-based medical devices. Sequencing theoretically grounded in Kingdon's Multiple Streams Framework and Rogers' Diffusion of Innovations theory. Modular architecture enables proportionate adoption across all regulatory maturity tiers**

## 5. Discussion

### 5.1 Regulatory Heterogeneity and its Systemic Consequences

The empirical findings reveal regulatory heterogeneity extending far beyond definitional differences into structural framework, institutional capacity and governance philosophy. The 3.34-point mean score disparity between Tier I countries (mean = 4.67) and Tier IV (mean = 1.33) represent not merely a policy gap but a systemic patient safety risk and access equity challenge. AI-based medical devices cleared in advanced regulatory environments carry no assurance of equivalent safety oversight in regulatory authorities operating under traditional medical device frameworks, creating a bifurcated global AI healthcare landscape that disproportionately disadvantages populations in lower-income countries.(88)

This heterogeneity simultaneously constrains innovation. The compliance burden of navigating nine distinct regulatory frameworks with inconsistent definitional frameworks, divergent technical evidence requirements and incompatible approval timelines is estimated to represent 15-20% of total product development costs in cross-country submissions. This burden creates rational incentives

to prioritize Tier I market approvals over emerging market deployment, perpetuating access inequities the harmonization roadmap is explicitly designed to address through modular adoption design.(89)

### 5.2 Four Independent Scholarly Contributions

This study makes four independent and original contributions to the literature on AI medical device governance, each verifiable through comparison with all prior publications identified in the structured literature review.(90,91)

The first contribution is the systematic nine-countries comparative regulatory matrix. By simultaneously evaluating nine diverse regulatory authorities against a consistent six-dimensional analytical framework using an inter-rater validated scoring rubric, this study provides the field's most comprehensive empirical mapping of global AI medical device regulatory readiness.

The second contribution is the validated five-point maturity scoring system ( $\kappa = 0.865$ ). This transforms inherently qualitative regulatory documents into a reproducible quantitative metric, enabling systematic cross-country comparison and longitudinal tracking previously unavailable to the field. The rubric's reliability substantially exceeds

conventional acceptability thresholds for qualitative policy research and its applicability extends beyond AI medical devices to comparative policy analysis in other emerging technology governance domains.(92) The third contribution is the original four-tier taxonomic classification of global AI medical device regulatory readiness. The Tier I-IV classification emerges empirically from scoring data and captures genuine qualitative discontinuities in regulatory framework. This classification provides a novel conceptual framework for regulators, manufacturers, and policymakers to calibrate expectations, identify peer-jurisdiction comparators, and sequence harmonization engagement with realistic expectations. The fourth contribution is the theoretically grounded seven-step harmonization roadmap. Unlike prior harmonization proposals that are either descriptively general or theoretically unanchored, this roadmap is explicitly sequenced according to Kingdon's Multiple Streams Framework and designed for diffusion-appropriate adoption according to Rogers' theory. This theoretical grounding provides the explanatory scaffolding justifying the roadmap's design logic, predicts its adoption dynamics, and enables evidence-based modification as real-world implementation proceeds.

### 5.3 Structured Implications for Practice, Policy and Research

The empirical and strategic contributions of this study carry direct and differentiated implications for three stakeholder communities whose decisions collectively determine the pace and coherence of global AI medical device regulatory harmonization. For policymakers and regulators, the findings define the specific governance dimensions requiring prioritized investment and the international coordination mechanisms most likely to accelerate convergence. For manufacturers, they clarify the compliance landscape that the harmonization roadmap will progressively reshape, enabling proactive investment in documentation and approval infrastructure. For research purposes, we highlight both the methodological innovations such as the validated maturity scoring system, the four-tier classification and the inter-rater reliability framework. These implications are not uniformly applicable across stakeholder groups or jurisdictional contexts; their relevance, urgency and feasibility vary systematically with regulatory maturity tier and institutional capacity. Table 7 presents them in structured form to maximize precision and actionability.

<b>Implication Type</b>	<b>Primary Stakeholder</b>	<b>Specific Recommendation</b>
<b>Policy Implications</b>	Regulators in Tier III-IV countries	<ul style="list-style-type: none"> <li>• Adopt the modular roadmap as a structured capacity-building scaffold.</li> <li>• Prioritize Steps 1–2 as entry points.</li> <li>• Leverage IMDRF reliance frameworks to accelerate Step 4 adoption without requiring full independent technical capability.</li> </ul>
<b>Policy Implications</b>	International standards bodies (ISO, IEC, IMDRF, WHO)	<ul style="list-style-type: none"> <li>• Accelerate development of AI-specific technical standards that operationalize common definitions (Step 1)</li> <li>• Prioritize post-market surveillance and lifecycle standards as the most globally underdeveloped governance dimension.</li> </ul>
<b>Regulatory Practice Implications</b>	National regulatory agencies (all tiers)	<ul style="list-style-type: none"> <li>• Integrate the six-dimensional regulatory readiness self-assessment as an annual benchmarking instrument.</li> <li>• Use the Tier I-IV classification to identify cross-country collaboration opportunities and capacity transfer arrangements.</li> </ul>
<b>Regulatory Practice Implications</b>	Multinational medical device manufacturers	<ul style="list-style-type: none"> <li>• Utilize the harmonization roadmap to anticipate future cross-country submission requirements.</li> <li>• Invest in PCCPs and lifecycle documentation as universal pre-submission infrastructure regardless of target market tier.</li> </ul>

<b>Research Agenda Implications</b>	Future regulatory science researchers	<ul style="list-style-type: none"> <li>• Conduct primary stakeholder interviews with regulatory officials across all the countries to validate gap findings.</li> <li>• Develop quantitative health economic modelling of the cost impact of regulatory fragmentation on AI device access in lower-income markets.</li> </ul>
<b>Research Agenda Implications</b>	Health informatics and regulatory science community	<ul style="list-style-type: none"> <li>• Extend the six-dimensional framework to include generative AI-specific governance dimensions.</li> <li>• Apply the maturity scoring methodology longitudinally to track regulatory convergence over 5-10 years horizons.</li> </ul>

**Table 7. Structured implications matrix: policy implications, regulatory practice implications, and research agenda implications for primary stakeholder groups**

#### 5.4 Institutionalizing Global Coordination

Step 7- institutionalizing a permanent global coordination platform is the most ambitious and most consequential roadmap component. Without a continuously adaptive governance mechanism, harmonization achievements are inherently fragile: national regulatory systems independently responding to new technological developments will inevitably diverge, as evidenced by the post-Brexit regulatory divergence between UK MHRA and EU MDR. (93)

The proposed platform would be structurally distinct from existing bodies such as IMDRF and WHO in three critical respects:

- It would maintain a living repository of real-time AI risk re-classifications and post-market performance findings rather than static guidance documents.
- It would possess the mandate and infrastructure to coordinate joint regulatory assessments for novel AI modalities including generative AI in clinical system.
- It would incorporate an explicit capacity-building function ensuring Tier III-IV countries are active participants in regulatory intelligence development rather than passive recipients of harmonized standards developed without their contextual input.

#### Conclusion

This study provides the most comprehensive empirical and strategic analysis of the global regulatory landscape for AI-based medical devices currently available in the scholarly literature. The findings confirm systemic fragmentation that a 3.34-point mean maturity disparity between the most and least advanced countries generates patient safety risks, constraining innovation and perpetuating inequitable access to AI-driven healthcare technologies.

The proposed seven-step strategic harmonization roadmap theoretically grounded in Kingdon's Multiple Streams Framework and Rogers' Diffusion of Innovations theory, empirically derived from a nine-countries inter-rater validated comparative assessment ( $\kappa = 0.865$ ). The proposed roadmap provides a comprehensive and implementable pathway toward globally coherent AI medical device governance across all regulatory maturity tiers

The four independent scholarly contributions of this study- the systematic comparative matrix, the validated maturity scoring system, the original four-tier taxonomic classification and the theoretically grounded harmonization roadmap collectively advance regulatory science. These directly serve regulators seeking structured capacity-building pathways, manufacturers requiring predictable global approval frameworks and patients who deserve timely access to safe, effective, and equitably governed AI-based medical technologies. As AI technologies evolve toward greater autonomy and clinical integration, the harmonization framework presented here provides the strategic foundation for a future in which regulatory oversight is globally cohesive, continuously adaptive and genuinely patient-centered.

**Acknowledgement:** This work was carried out as part of the authors' independent academic research. No external funding, institutional support, or third-party involvement influenced the design, analysis, or reporting of the study.

**Author Contribution:** Dr. Viney Lather and Dr. P.S Chandranand conceptualized the study. Shivali Rahi and Dr. P.S Chandranand contributed to the design of the work, researched all sections and drafted the original. Dr. P.S Chandranand and Dr. Arpana Rana assisted with methodology design, provided regulatory insights. All authors have read and approved the final version of the manuscript.

**Funding:** There is no funding involved in this work.

**Conflict of interest:** The authors declare no conflict of interest.

## REFERENCES

- Obermeyer Z, Emanuel EJ. Predicting the Future- Big Data, Machine Learning, and Clinical Medicine. *N Engl J Med*. 2016 Sep 29;375(13):1216–9. doi:10.1056/NEJMp1606181 PubMed PMID: 27682033; PubMed Central PMCID: PMC5070532.
- Topol EJ. High-performance medicine: the convergence of human and artificial intelligence. *Nat Med*. 2019 Jan;25(1):44–56. doi:10.1038/s41591-018-0300-7 PubMed PMID: 30617339.
- Tetty-Engmann F, Parupelli SK, Bauer SR, Bhattarai N, Desai S. Advances in Artificial Intelligence-Based Medical Devices for Healthcare Applications. *Biomed Mater Devices*. 2026 Jun 1;4(2):1767–87. doi:10.1007/s44174-025-00379-1
- Panda A. Artificial Intelligence in Medical Devices - An Extensive Study. *Corpbiz* [Internet]. 2023 Feb 6 [cited 2026 Apr 1]. Available from: <https://corpbiz.io/learning/artificial-intelligence-in-medical-devices-an-extensive-study/>
- Santra S, Kukreja P, Saxena K, Gandhi S, Singh OV. Navigating regulatory and policy challenges for AI enabled combination devices. *Front Med Technol*. 2024 Nov 28;6:1473350. doi:10.3389/fmedt.2024.1473350 PubMed PMID: 39669903; PubMed Central PMCID: PMC11634576.
- McKee M, Wouters OJ. The Challenges of Regulating Artificial Intelligence in Healthcare. *Int J Health Policy Manag*. 2022 Sep 19;12:7261. doi:10.34172/ijhpm.2022.7261 PubMed PMID: 36243948; PubMed Central PMCID: PMC10125205.
- Palama V. Regulatory Fragmentation in Healthcare AI: A Policy Review of FDA Oversight, HIPAA, and Implementation Barriers. *Int J Technol Manag Humanit*. 2026 Jan 14;12(01):1–10. doi:10.21590/ijtmh.12.01.01
- Jurczak KM, van der Boon TAB, Devia-Rodriguez R, Schuurmann RCL, Sjollem J, van Huizen L, et al. Recent regulatory developments in EU Medical Device Regulation and their impact on biomaterials translation. *Bioeng Transl Med*. 2024 Oct 16;10(2):e10721. doi:10.1002/btm2.10721 PubMed PMID: 40060767; PubMed Central PMCID: PMC11883120.
- Laczkó M, Pfluege F. The EU's 2025 proposal to simplify the Medical and In-Vitro-Diagnostic Devices Regulations (MDR/IVDR). *Healthcare & Life Sciences Blog* [Internet]. 2025 Dec 19 [cited 2026 Apr 2]. Available from: <https://healthcarelifesciences.bakermckenzie.com/2025/12/19/the-eus-2025-proposal-to-simplify-the-medical-and-in-vitro-diagnostic-devices-regulations-mdr-ivdr/>
- Good Machine Learning Practice for Medical Device Development: Guiding Principles [Internet]. USFDA; 2025 [cited 2026 Apr 1]. Available from: <https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles>
- Health C for D and R. Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions [Internet]. FDA; 2025 [cited 2026 Apr 1]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/marketing-submission-recommendations-predetermined-change-control-plan-artificial-intelligence>
- Varela J, Chijian Y. The EU AI Act's impact on medical devices. *PharmaLex* [Internet]. 2025 Mar 28 [cited 2026 Apr 1]. Available from: <https://www.pharmalex.com/thought-leadership/blogs/what-global-ai-regulations-mean-for-medical-device-manufacturers/>
- Reddy S. Navigating the AI Revolution: The Case for Precise Regulation in Health Care. *J Med Internet Res*. 2023 Sep 11;25:e49989. doi:10.2196/49989 PubMed PMID: 37695650; PubMed Central PMCID: PMC10520760.
- Therapeutic Goods Administration (TGA). Standards for software-based medical devices [text] [Internet]. Therapeutic Goods Administration (TGA); 2026 [cited 2026 Apr 28]. Available from: <https://www.tga.gov.au/products/medical-devices/software-and-artificial-intelligence-ai/overview/standards-software-based-medical-devices>
- Kulshreshtha A, Bharadwaj M. The global regulatory landscape for AI/ML-enabled devices. Vol. 4. 2024 Sep;4(3):5–20. doi:https://www.raps.org/News-and-Articles/News-

- Articles/2024/9/Theglobal-regulatory-landscape-for-AI-ML-enabled
16. Badnjević A, Avdihodžić H, Gurbeta Pokvić L. ARTIFICIAL INTELLIGENCE IN MEDICAL DEVICES: PAST, PRESENT AND FUTURE. *Psychiatr Danub*. 2021 May;33(Suppl 3):S336–41. doi:10.5005/sar-1-1-2-101 PubMed PMID: 34010259.
  17. Bianchini E, Mayer CC. Medical Device Regulation: Should We Care About It? *Artery Res*. 2022;28(2):55–60. doi:10.1007/s44200-022-00014-0 PubMed PMID: 35378951; PubMed Central PMCID: PMC8968778.
  18. Ramírez PB. Global Harmony or Regulatory Chaos? AI's Role in Unifying Medical Device Laws [Internet]. 2024 [cited 2026 Apr 1]. Available from: <https://www.linkedin.com/pulse/global-harmony-regulatory-chaos-ais-role-unifying-medical-ram%C3%ADrez-gw7ac>
  19. Gupta SK. Medical Device Regulations: A Current Perspective. *J Young Pharm*. 2015 Nov 21;8(1):6–11. doi:10.5530/jyp.2016.1.3
  20. Ebad SA, Alhashmi A, Amara M, Miled AB, Saqib M. Artificial Intelligence-Based Software as a Medical Device (AI-SaMD): A Systematic Review. *Healthcare*. 2025 Apr 3;13(7):817. doi:10.3390/healthcare13070817 PubMed PMID: 40218113; PubMed Central PMCID: PMC11988595.
  21. Palaniappan K, Lin EYT, Vogel S. Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector. *Healthcare*. 2024 Jan;12(5):562. doi:10.3390/healthcare12050562
  22. Rajagopal A, Ayanian S, Ryu AJ, Qian R, Legler SR, Peeler EA, et al. Machine Learning Operations in Health Care: A Scoping Review. *Mayo Clin Proc Digit Health*. 2024 Jul 14;2(3):421–37. doi:10.1016/j.mcpdig.2024.06.009 PubMed PMID: 40206123; PubMed Central PMCID: PMC11975983.
  23. Aarab A, El Marzouki A, Boubker O, El Moutaqi B. Integrating AI in Public Governance: A Systematic Review. *Digital*. 2025 Dec;5(4):59. doi:10.3390/digital5040059
  24. Ackerman W, Danzis S, Kuhn C, Dworkin O. Framework for the Future of AI: Senator Cassidy Issues White Paper, Seeks Public Feedback. *Covington Digital Health* [Internet]. 2023 Sep 11 [cited 2026 Apr 1]. Available from: <https://www.covingtondigitalhealth.com/2023/09/framework-for-the-future-of-ai-senator-cassidy-issues-white-paper-seeks-public-feedback/>
  25. Granlund T, Stirbu V, Mikkonen T. Toward a Regulatory-Compliant Lifecycle for Artificial-Intelligence-Based Medical Devices in the European Union: Industry Perspectives. *Computer*. 2024 Sep;57(9):24–34. doi:10.1109/MC.2024.3414368
  26. Siddle MTL, Caldwell M, Geringer N. Lexology [Internet]. 2025 [cited 2026 Apr 1]. AI-Enabled Medical Devices: Transformation and Regulation. Available from: <https://www.lexology.com/library/detail.aspx?g=f133ee05-a503-4aae-8d28-08a8db48d184>
  27. World Health Organization. Regulatory considerations on artificial intelligence for health [Internet]. Geneva; 2023. Available from: <https://iris.who.int/server/api/core/bitstreams/ad62580f-540f-4e36-b957-e7f2946ae1fb/content>
  28. Health C for D and R. FDA [Internet]. FDA; 2023 [cited 2026 Apr 1]. Total Product Life Cycle for Medical Devices. Available from: <https://www.fda.gov/about-fda/cdrh-transparency/total-product-life-cycle-medical-devices>
  29. Health C for D and R. Artificial Intelligence in Software as a Medical Device. FDA [Internet]. 2025 Jul 10 [cited 2026 Apr 1]. Available from: <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-software-medical-device>
  30. Muehlematter UJ, Daniore P, Vokinger KN. Approval of artificial intelligence and machine learning-based medical devices in the USA and Europe (2015-20): a comparative analysis. *Lancet Digit Health*. 2021 Mar;3(3):e195–203. doi:10.1016/S2589-7500(20)30292-2 PubMed PMID: 33478929.
  31. Zhang S, Li Y, Liu W, Chu Q, Wang S, Li J, et al. A decade of review in global regulation and research of artificial intelligence medical devices (2015–2025). *Front Med*. 2025 Jul 17;12:1630408. doi:10.3389/fmed.2025.1630408 PubMed PMID: 40747091; PubMed Central PMCID: PMC12310608.
  32. Calvin W L Ho. Implementing the human right to science in the regulatory governance of artificial intelligence in healthcare. *J Law Biosci*. 2023 Dec;10(2). doi:https://doi.org/10.1093/jlb/lsad026
  33. Singhal A, Neveditsin N, Tanveer H, Mago V. Toward Fairness, Accountability, Transparency,

- and Ethics in AI for Social Media and Health Care: Scoping Review. *JMIR Med Inform.* 2024 Apr 3;12:e50048. doi:10.2196/50048 PubMed PMID: 38568737; PubMed Central PMCID: PMC11024755.
34. Maccaro A, Stokes K, Statham L, He L, Williams A, Pecchia L, et al. Clearing the Fog: A Scoping Literature Review on the Ethical Issues Surrounding Artificial Intelligence-Based Medical Devices. *J Pers Med.* 2024 Apr 23;14(5):443. doi:10.3390/jpm14050443 PubMed PMID: 38793025; PubMed Central PMCID: PMC11121798.
  35. Marey A, Arjmand P, Alerab ADS, Eslami MJ, Saad AM, Sanchez N, et al. Explainability, transparency and black box challenges of AI in radiology: impact on patient care in cardiovascular radiology. *Egypt J Radiol Nucl Med.* 2024 Sep 13;55(1):183. doi:10.1186/s43055-024-01356-2
  36. Trevino M. AI In Medical Devices: Meeting The Regulatory Challenge Around The World [Internet]. 2025 May 1 [cited 2026 Apr 1]. Available from: <https://www.meddeviceonline.com/doc/ai-in-medical-devices-meeting-the-regulatory-challenge-around-the-world-part-0001>
  37. Benjamins S, Dhunoo P, Meskó B. The state of artificial intelligence-based FDA-approved medical devices and algorithms: an online database. *NPJ Digit Med.* 2020;3:118. doi:10.1038/s41746-020-00324-0 PubMed PMID: 32984550; PubMed Central PMCID: PMC7486909.
  38. Gerke S, Babic B, Evgeniou T, Cohen IG. The need for a system view to regulate artificial intelligence/machine learning-based software as medical device. *Npj Digit Med.* 2020 Apr 7;3(1):53. doi:10.1038/s41746-020-0262-2
  39. Char DS, Shah NH, Magnus D. Implementing Machine Learning in Health Care – Addressing Ethical Challenges. *N Engl J Med.* 2018 Mar 15;378(11):981–3. doi:10.1056/NEJMp1714229
  40. Finch WW, Butt M. Gaps in AI-Compliant Complementary Governance Frameworks' Suitability (for Low-Capacity Actors), and Structural Asymmetries (in the Compliance Ecosystem) – A Systematic Review. *J Cybersecurity Priv.* 2025 Dec;5(4):101. doi:10.3390/jcp5040101
  41. WHO guidance. Ethics and governance of artificial intelligence for health [Internet]. 2021 [cited 2026 Apr 2]. Available from: <https://www.who.int/publications/i/item/9789240029200>
  42. US FDA Artificial Intelligence and Machine Learning Discussion Paper [Internet]. [cited 2026 Apr 2]. Available from: <https://www.fda.gov/files/medical%20devices/published/US-FDA-Artificial-Intelligence-and-Machine-Learning-Discussion-Paper.pdf>
  43. Hoefer R. The Multiple Streams Framework: Understanding and Applying the Problems, Policies, and Politics Approach. *J Policy Pract Res.* 2022;3(1):1–5. doi:10.1007/s42972-022-00049-2 PubMed PMID: null; PubMed Central PMCID: PMC8861624.
  44. Battaglia F. Kingdon at 40: multiple streams, multiple flaws. *J Policy Stud.* 2025;40(3):25–42. doi:10.52372/jps.250204
  45. Halton C. Investopedia [Internet]. 2026 [cited 2026 Apr 2]. Understanding the Diffusion of Innovations Theory with Examples. Available from: <https://www.investopedia.com/terms/d/diffusion-of-innovations-theory.asp>
  46. Ullagaddi P. Cross-Regional Analysis of Global AI Healthcare Regulation. *J Comput Commun.* 2025 Jan 1. doi:10.4236/JCC.2025.135005
  47. Health C for D and R. Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations [Internet]. FDA; 2025 [cited 2026 Apr 27]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/artificial-intelligence-enabled-device-software-functions-lifecycle-management-and-marketing>
  48. Health C for D and R. FDA [Internet]. FDA; 2026 [cited 2026 Apr 27]. Quality Management System Regulation (QMSR). Available from: <https://www.fda.gov/medical-devices/postmarket-requirements-devices/quality-management-system-regulation-qmsr>
  49. Health C for D and R. FDA [Internet]. FDA; 2026 [cited 2026 Apr 28]. Artificial Intelligence-Enabled Medical Devices. Available from: <https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-enabled-medical-devices>
  50. Sandalow M, Adams K, Loud G. FDA Oversight: Understanding the Regulation of Health AI Tools. Bipartisan Policy Center [Internet]. 2025 Nov 10 [cited 2026 Apr 27].

- Available from: <https://bipartisanpolicy.org/issue-brief/fda-oversight-understanding-the-regulation-of-health-ai-tools/>
51. Klemann T. The EU's AI Act and Medical Device Regulation. MEDiCept [Internet]. 2024 Mar 6 [cited 2026 Apr 1]. Available from: <https://www.mediccept.com/eu-ai-act-and-its-impact-on-the-medical-device-industry/>
  52. Official Journal of the European Union. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance. ). OJ L [Internet]. 2017 Apr 5. p. 1-175. Available from: <http://data.europa.eu/eli/reg/2017/745/oj>
  53. van Kolschooten H, van Oirschot J. The EU Artificial Intelligence Act (2024): Implications for healthcare. Health Policy. 2024 Nov;149:105152. doi:10.1016/j.healthpol.2024.105152 PubMed PMID: 39244818.
  54. Interplay between the Medical Devices Regulation (MDR) & In vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA) [Internet]. [cited 2026 Apr 26]. Available from: [https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4\\_en?filename=mdcg\\_2025-6\\_en.pdf](https://health.ec.europa.eu/document/download/b78a17d7-e3cd-4943-851d-e02a2f22bbb4_en?filename=mdcg_2025-6_en.pdf)
  55. Boland H. www.hoganlovells.com [Internet]. 2025 [cited 2026 Apr 26]. MDCG published new guidance on the interplay between the MDR & IVDR and the AI Act. Available from: <https://www.hoganlovells.com/en/publications/mdcg-published-new-guidance-on-the-interplay-between-the-mdr-ivdr-and-the-ai-act>
  56. Laczkó FP Máté. The EU's 2025 proposal to simplify the Medical and In-Vitro-Diagnostic Devices Regulations (MDR/IVDR). Healthcare & Life Sciences Blog [Internet]. 2025 Dec 19 [cited 2026 Apr 26]. Available from: <https://healthcarelifesciences.bakermckenzie.com/2025/12/19/the-eus-2025-proposal-to-simplify-the-medical-and-in-vitro-diagnostic-devices-regulations-mdr-ivdr/>
  57. Davis M. PMDA Approach to Artificial Intelligence (AI) based Medical Devices. Global Regulatory Partners, Inc. [Internet]. 2020 Mar 2 [cited 2026 Apr 1]. Available from: <https://globalregulatorypartners.com/pmda-approach-to-artificial-intelligence-ai-based-medical-devices/>
  58. Imagawa K. Regulatory framework for innovative medical devices (ex. SaMD, AI) [Internet]. The 9th Thailand - Japan Symposium 2023. 2023. Available from: <https://www.pmda.go.jp/files/000266836.pdf>
  59. Nakano S. DIA Global Forum [Internet]. 2021 [cited 2026 Apr 1]. Policies to Promote Development of AI-Based Medical Devices in Japan. Available from: <https://globalforum.diaglobal.org/issue/november-2021/policies-to-promote-development-of-ai-based-medical-devices-in-japan/>
  60. Medicines & Healthcare products Regulatory Agency. GOV.UK [Internet]. 2023 [cited 2026 Apr 1]. Software and AI as a Medical Device Change Programme roadmap. Available from: <https://www.gov.uk/government/publications/software-and-ai-as-a-medical-device-change-programme/software-and-ai-as-a-medical-device-change-programme-roadmap>
  61. RegDesk. MHRA Guidance on Software and AI as a Medical Device. RegDesk [Internet]. 2025 Mar 5 [cited 2026 Apr 1]. Available from: <https://www.regdesk.co/blog/mhra-guidance-on-software-and-ai-as-a-medical-device/>
  62. Reid R. 2025 in MedTech: a year of innovation, global leadership and regulatory milestones [Internet]. 2025 [cited 2026 Apr 26]. Available from: <https://medregs.blog.gov.uk/2025/12/22/2025-in-medtech-a-year-of-innovation-global-leadership-and-regulatory-milestones/>
  63. Godbeer L. AI Airlock: MHRA's Approach to AI in Healthcare. DLRC [Internet]. 2025 Oct 1 [cited 2026 Apr 26]. Available from: <https://www.dlrcgroup.com/ai-airlock-mhras-approach-to-ai-in-healthcare/>
  64. Hill K. Emergo by UL [Internet]. 2024 [cited 2026 Apr 26]. MHRA Publishes Revised Roadmap of Future Regulatory Framework for Medical Devices. Available from: <https://www.emergobyul.com/news/mhra-publishes-revised-roadmap-future-regulatory-framework-medical-devices>
  65. Wray GR, Vila EC, Fuhrmann B. BLG [Internet]. 2025 [cited 2026 Apr 1]. Health Canada's evolving regulatory framework for machine learning-enabled medical devices. Available from: <https://www.blg.com/en/insights/2025/02/h>

- health-canadas-evolving-regulatory-framework-for-machine-learning-enabled-medical-devices
66. Reuter E. FDA, Health Canada give sneak peek into future AI regs | MedTech Dive [Internet]. 2024 [cited 2026 Apr 1]. Available from: <https://www.medtechdive.com/news/fda-health-canada-future-ai-regulations/729953/>
  67. Arai M. What's Next After AIDA? [Internet]. Schwartz Reisman Institute for technology and society; 2025 [cited 2026 Apr 26]. Available from: <https://srinstitute.utoronto.ca/news/whats-next-for-aida>
  68. Ishaque AH, Aidid A, Zadeh G. Lessons from the Failure of Canada's Artificial Intelligence and Data Act. *NEJM AI*. 2025 Jun 26;2(7):AIpc2500153. doi:10.1056/AIpc2500153
  69. Burnett TC, Carroll V, Lapner M, Kenna AWM. Gowling WLG [Internet]. 2025 [cited 2026 Apr 26]. Guide to Healthcare AI 2025: Legal framework, trends & developments. Available from: <https://gowlingwlg.com/insights-resources/guides/2025/guide-to-healthcare-ai-2025>
  70. Han Y, Ceross A, Bergmann J. Regulatory Frameworks for AI-Enabled Medical Device Software in China: Comparative Analysis and Review of Implications for Global Manufacturer. *JMIR AI*. 2024 Jul 29;3(1):e46871. doi:10.2196/46871
  71. King H. Regulatory update for SaMD and AI product approvals in China. Vol. 1. 2021 Jun;1(2):33-41.
  72. Sheehan M. Tracing the Roots of China's AI Regulations. *Carnegie Endow Int Peace* [Internet]. 2024 Feb 27 [cited 2026 Apr 1]. Available from: <https://carnegieendowment.org/research/2024/02/tracing-the-roots-of-chinas-ai-regulations>
  73. Liang J. Australia's Current Regulatory Position on AI Medical Devices. *Asia Actual* [Internet]. 2026 Feb 10 [cited 2026 Apr 1]. Available from: <https://asiaactual.com/blog/australias-current-regulatory-position-on-ai-medical-devices/>
  74. Therapeutic Goods Administration (TGA). Artificial intelligence (AI) and medical device software regulation [text] [Internet]. Therapeutic Goods Administration (TGA); 2026 [cited 2026 Apr 1]. Available from: <https://www.tga.gov.au/products/medical-devices/software-and-artificial-intelligence-ai/manufacturing/artificial-intelligence-ai-and-medical-device-software-regulation>
  75. Regulatory Guidelines for Software Medical Devices including Machine Learning-Enabled Medical Devices - A Life Cycle Approach.pdf [Internet]. [cited 2026 Apr 26]. Available from: [https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gl-04-r4-regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach-\(2025-dec\)-pub.pdf](https://www.hsa.gov.sg/docs/default-source/hprg-mdb/guidance-documents-for-medical-devices/gl-04-r4-regulatory-guidelines-for-software-medical-devices---a-life-cycle-approach-(2025-dec)-pub.pdf)
  76. Anle L. Current Regulatory Approaches for AI Medical Devices in Singapore [Internet]. 2022 Sep 12. Available from: [https://www.imdrf.org/sites/default/files/2022-09/Lin%20Anle\\_0.pdf](https://www.imdrf.org/sites/default/files/2022-09/Lin%20Anle_0.pdf)
  77. Chew R, Hann LW. HSA Consults on Exempting an AI-Software as a Medical Device Developed in Public Healthcare from Licensing and Registration Requirements. *Rajah & Tann Asia* [Internet]. 2025 Jul 11 [cited 2026 Apr 2]. Available from: <https://www.rajahtannasia.com/viewpoints/hsa-consults-on-exempting-an-ai-software-as-a-medical-device-developed-in-public-healthcare-from-licensing-and-registration-requirements/>
  78. Singapore HSA 2025 SaMD & CDSS Guidelines Update [Internet]. 2025 [cited 2026 Apr 26]. Available from: <https://www.pureglobal.com/news/singapore-hsa-2025-samd-cdss-guidelines-update>
  79. Lee S. Singapore-Malaysia Formalize Medical Device Reliance. *Asia Actual* [Internet]. 2026 Mar 10 [cited 2026 Apr 26]. Available from: <https://asiaactual.com/blog/mda-verification-route-singapore-hsa-reliance/>
  80. Medical Devices Rules, 2017.pdf [Internet]. [cited 2026 Apr 2]. Available from: [https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m\\_device/Medical%20Devices%20Rules,%202017.pdf](https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2022/m_device/Medical%20Devices%20Rules,%202017.pdf)
  81. Draft guidance document on Medical Device Software, 2025.pdf [Internet]. [cited 2026 Apr 26]. Available from: [https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic\\_NoticesFiles/Draft%20guidance%20document%20on%20Medical%20Device%20Software%202021%2010%202025.pdf](https://cdsco.gov.in/opencms/resources/UploadCDSCOWeb/2018/UploadPublic_NoticesFiles/Draft%20guidance%20document%20on%20Medical%20Device%20Software%202021%2010%202025.pdf)
  82. Koul S. Business Standard [Internet]. 2025 [cited 2026 Apr 26]. CDSCO issues draft guidelines to regulate medical device software. Available from: <https://www.business-standard.com/industry/news/cdsco-draft->

- guidelines-medical-device-software-regulation-ai-ml-125102200764\_1.html
83. Pujari R. India - Medical Device As Software: Has CDSCO Guidance Changed The Rules? *Conventus Law* [Internet]. 2026 Feb 3 [cited 2026 Apr 2]. Available from: <https://conventuslaw.com/report/india-medical-device-as-software-has-cdscoguidance-changed-the-rules/>
84. Verma G. India Releases Draft Guidance on Medical Device Software [Internet]. 2025 [cited 2026 Apr 2]. Available from: <https://asiaactual.com/blog/india-releases-draft-guidance-on-medical-device-software/>
85. Larson DB, Harvey H, Rubin DL, Irani N, Tse JR, Langlotz CP. Regulatory Frameworks for Development and Evaluation of Artificial Intelligence-Based Diagnostic Imaging Algorithms: Summary and Recommendations. *J Am Coll Radiol JACR*. 2021 Mar;18(3 Pt A):413–24. doi:10.1016/j.jacr.2020.09.060 PubMed PMID: 33096088; PubMed Central PMCID: PMC7574690.
86. Palaniappan K, Lin EYT, Vogel S, Lim JCW. Gaps in the Global Regulatory Frameworks for the Use of Artificial Intelligence (AI) in the Healthcare Services Sector and Key Recommendations. *Healthcare*. 2024 Aug 30;12(17):1730. doi:10.3390/healthcare12171730 PubMed PMID: 39273754; PubMed Central PMCID: PMC11394803.
87. Zhou K, Gattinger G. The Evolving Regulatory Paradigm of AI in MedTech: A Review of Perspectives and Where We Are Today. *Ther Innov Regul Sci*. 2024;58(3):456–64. doi:10.1007/s43441-024-00628-3 PubMed PMID: 38528278; PubMed Central PMCID: PMC11043174.
88. Chakraborty A, Karhade M. Global AI Governance in Healthcare: A Cross-Jurisdictional Regulatory Analysis [Internet]. 2024. Available from: [https://www.researchgate.net/publication/381404246\\_Global\\_AI\\_Governance\\_in\\_Healthcare\\_A\\_Cross-Jurisdictional\\_Regulatory\\_Analysis](https://www.researchgate.net/publication/381404246_Global_AI_Governance_in_Healthcare_A_Cross-Jurisdictional_Regulatory_Analysis) doi:10.48550/arXiv.2406.08695
89. Muralidharan V, Adewale BA, Huang CJ, Nta MT, Ademiju PO, Pathmarajah P, et al. A scoping review of reporting gaps in FDA-approved AI medical devices. *Npj Digit Med*. 2024 Oct 3;7(1):273. doi:10.1038/s41746-024-01270-x
90. Han Y, Bergmann JHM. Transforming Medical Regulations into Numbers: Vectorizing a Decade of Medical Device Regulatory Shifts in the USA, EU, and China. *ACM Trans Comput Healthc*. 2026 Mar 17;7(2):23:1-23:34. doi:10.1145/3793533
91. Mennella C, Maniscalco U, De Pietro G, Esposito M. Ethical and regulatory challenges of AI technologies in healthcare: A narrative review. *Heliyon*. 2024 Feb 15;10(4):e26297. doi:10.1016/j.heliyon.2024.e26297 PubMed PMID: 38384518; PubMed Central PMCID: PMC10879008.
92. Allen B. Medical device cybersecurity maturity industry benchmark report [Internet]. The Medical Device Innovation Consortium; 2022 Oct. Available from: [https://mdic.org/wp-content/uploads/2022/10/test2Final\\_MDIC-Cybersecurity-Benchmarking-Report\\_Overview\\_2022091227.pdf](https://mdic.org/wp-content/uploads/2022/10/test2Final_MDIC-Cybersecurity-Benchmarking-Report_Overview_2022091227.pdf)
93. Singh M. Evolving Ethical and Regulatory Framework for Artificial Intelligence for Health. *Int J Res Appl Sci Eng Technol*. 2021;9(6). doi:10.22214/ijraset.2021.35428