

GLOBAL REGULATORY INTELLIGENCE · 2026

2026 Regulatory Updates: Submission Builder Wizards for New Registration

Impact Assessment for Medical Device Registration & eSubmission Systems

Published July 2026 · RegDesk Platform Intelligence · Covers 16 Markets · 4 Regions

40+

REGULATORY UPDATES

16

MARKETS COVERED

4

REGIONS ANALYZED

18

HIGH-IMPACT CHANGES

EXECUTIVE SUMMARY

- **USA (FDA):** eSTAR v7.0 mandatory from August 3, 2026, integrating updated Human Factors guidance; submissions in older versions risk additional information requests.
- **EU (MDR/IVDR):** EUDAMED first four modules became mandatory May 28, 2026 — Actor Registration, UDI/Devices, Notified Bodies & Certificates, and Market Surveillance. Legacy device deadline: November 27, 2026.
- **Canada:** Mandatory digital submissions via REP/CESG portal from January 2026; IMDRF Table of Contents adopted; MDEL Phase 2 amendments effective December 14, 2026.
- **Japan (PMDA):** eCTD v4.0 is the sole mandatory submission format for all new applications from April 1, 2026 — first major authority to fully implement next-generation eCTD.
- **UK (MHRA):** Draft Medical Devices (Amendment) Regulations 2026 published — introducing international reliance pathway, mandatory UDI, IMDRF-aligned classification, cybersecurity for SaMD, and PCCPs.
- **UAE:** Major authority shift — Emirates Drug Establishment (EDE) replaces MOHAP as the sole federal authority; all submissions now exclusively through the EDE digital portal.
- **Australia (TGA):** UDI mandatory for Class IIb and Class III devices from July 1, 2026; UDI data submission to AusUDID required; AI-enabled SaMD guidance updated February 2026.
- **Malaysia (MDA):** Mandatory registration number on device labels by July 31, 2026; aesthetic devices newly designated as medical devices from June 1, 2026.
- **India (CDSCO):** All imported medical devices require official import license via SUGAM portal from 2026; SaMD regulatory framework formalized with four-tier risk classification.
- **Brazil (ANVISA):** UDI data transmission via SIUD database mandatory from March 1, 2026; MDSAP participation being pushed for international manufacturers in 2026–2027 agenda.

AMERICAS USA · Canada · Brazil · Mexico

Country	Authority	Update / Change	Effective Date	Impact Area	Description
USA	FDA	eSTAR v7.0 Released & Mandatory	Aug 3, 2026	Portal/eSubmission	eSTAR v7.0 (released June 1, 2026) becomes the sole accepted format on August 3, 2026. Old v6.x submissions retired. All 510(k), De Novo, and PMA submissions must use v7.0 or risk additional information requests.
USA	FDA	Human Factors Content Guidance Integration	Aug 1, 2026	Technical File Portal/eSubmission	eSTAR v7.0 (nIVD and IVD templates) now prompts manufacturers to identify the appropriate Human Factors Submission Category and provide supporting evidence per the FDA's Human Factors Content Guidance (effective August 1, 2026). New mandatory wizard sections added.
USA	FDA	PreSTAR v3.0 Updated	Jun 1, 2026	Portal/eSubmission	Alongside eSTAR v7.0, PreSTAR v3.0 was released for Pre-Submissions (Q-Subs), aligning the pre-submission template with the new Human Factors and PMA facility information updates.
USA	FDA	PMA Facility Information Update	Jun 1, 2026	Technical File	Updates to PMA supplement facility information requirements, particularly for the addition of new manufacturing facilities. The eSTAR submission wizard now includes revised facility fields for PMA applicants.
Canada	Health Canada	Mandatory Digital Submissions via REP/CESG	Jan 2026	Portal/eSubmission	All Class II, III, and IV medical device submissions and amendments must be submitted through the web-based Regulatory Enrolment Process (REP) and Common Electronic Submissions Gateway (CESG). Email submissions are no longer accepted. Extended to MDEL applications from April 2026.
Canada	Health Canada	Managing Applications Guidance v5 (New Screening Rules)	Feb 2, 2026	Technical File Transition/Deadline	New guidance version 5 introduces stricter screening procedures and tighter response timelines for Class II–IV applications. Applies to all new, in-progress, and reconsideration requests. Incomplete submissions returned faster.
Canada	Health Canada	IMDRF Table of Contents Adopted	2026	Technical File	Health Canada has adopted the IMDRF Table of Contents structure for submission dossiers, promoting global harmonization. Submission Builder wizards must align technical file organization to the IMDRF ToC format.
Canada	Health Canada	MDEL Phase 2 Modernization — Mandatory Supplier Lists	Dec 14, 2026	Technical File	SOR/2026-110 introduces mandatory supplier lists (name, address, device risk class) as part of MDEL applications. MDEL holders must establish documented procedures for distribution records, incident reporting, and corrective actions.
Canada	Health Canada	Terms & Conditions (T&C) Framework for Licences	Jan 1, 2026	Transition/Deadline	Health Canada can now impose legally binding terms and conditions on Class II–IV device licences at any lifecycle stage. New regulatory risk affecting post-approval compliance obligations and submission strategies.
Brazil	ANVISA	UDI Data Transmission Mandatory (SIUD)	Mar 1, 2026	UDI	Normative Instruction 426/2026 makes transmission of UDI data to Brazil's SIUD database mandatory under RDC 591/2021. Manufacturers must submit UDI-DI and related data before placing devices on the Brazilian market.
Brazil	ANVISA	2026–2027 Regulatory Agenda Priorities (Ordinance 1.484/2025)	Jan 1, 2026	Portal/eSubmission Classification	Key 2026 priorities include public UDI databases, mandatory MDSAP for international manufacturers, streamlined borderline product classification, and new SaMD/AI-ML device regulations. Impacts how submissions are structured in Solicita portal.
Brazil	ANVISA	Regulatory Reliance Pathway (IN 290/2024) Operationalized	2026 (active)	Transition/Deadline	Class III & IV devices with prior authorization from AREE (Australia, Canada, USA, Japan) can use the expedited reliance route. Full technical dossier per RDC 751/2022 or RDC 830/2023 still required. Amendment process introduced for reliance requests.
Mexico	COFEPRIS	NOM-137-SSA1-2025 — New Labeling Standard	May 2026	Labeling	Final NOM-137-SSA1-2025 labeling standard published May 2026. New definitions, specific requirements for IFUs and kit labeling in Spanish. All medical device labels must comply; IFU must be included in Spanish.
Mexico	COFEPRIS	Expanded Equivalency Route (Abbreviated Pathway)	2026 (active)	Portal/eSubmission Transition/Deadline	Fast-track registration for devices approved by FDA, Health Canada, PMDA, EMA, TGA, MFDS, NMPA, ANVISA, and other IMDRF/MDSAP authorities. Unified dossier structure; COFEPRIS targets 30 business day review. DIGIPRIS portal used for electronic submissions.
Mexico	COFEPRIS	Registration Renewal Extended to 10 Years	Jan 2026	Transition/Deadline	General Health Law reform allows renewals for up to 10 years (initial registrations remain 5 years). Impacts long-term regulatory planning for devices already registered in Mexico.



EUROPE European Union · United Kingdom

Country	Authority	Update / Change	Effective Date	Impact Area	Description
EU	EC / MDR / IVDR	EUDAMED — First 4 Modules Mandatory	May 28, 2026	Portal/eSubmission UDI	Four EUDAMED modules became legally mandatory: (1) Actor Registration, (2) UDI/Devices Registration, (3) Notified Bodies & Certificates, (4) Market Surveillance. All new devices must be fully registered in EUDAMED before EU market placement.
EU	EC / MDR / IVDR	EUDAMED — Legacy Device Registration Deadline	Nov 27/28, 2026	Transition/Deadline Portal/eSubmission	Devices CE marked and placed on the market before May 28, 2026 (legacy devices) must be fully registered in EUDAMED by November 27/28, 2026. Non-compliance risks market access suspension.
EU	EC / MDR / IVDR	Mandatory UDI Registration in EUDAMED (UDI/Device Module)	May 28, 2026	UDI	Manufacturers must register UDI-DI data (including device identifiers and basic UDI-DI) in the EUDAMED UDI/Devices module as a prerequisite for CE marking and EU market access. Replaces previous voluntary EUDAMED use.
EU	EC / MDR / IVDR	Certificate & NB Information in EUDAMED	May 28, 2026	Portal/eSubmission	Notified Bodies must upload certificate data (issuance, scope, suspension, withdrawal) to the EUDAMED Notified Bodies & Certificates module. Manufacturers must ensure their NB is compliant to avoid delays in certificate visibility.
UK	MHRA	Medical Devices (Amendment) Regulations 2026 — Draft Published	Dec 2026 (proposed)	Transition/Deadline Technical File	Draft statutory instrument published in 2026 to modernize GB medical device regulations. Anticipated entry into force June 2027. Three-year transition for general devices; five-year for IVDs. Introduces international reliance pathway, strengthened essential requirements, and enhanced technical documentation.
UK	MHRA	Mandatory UDI for Great Britain	2026 (proposed)	UDI	The new UK regulations mandate compulsory UDI for all devices throughout the entire lifecycle, ensuring end-to-end traceability in the GB market. Submission wizards will need to include UDI fields as mandatory for GB registrations.
UK	MHRA	International Reliance Pathway — New Fast Track	2026 (proposed)	Classification Transition/Deadline	New pathway enables faster GB market access for devices already approved in Australia, Canada, or the USA. Submission wizards will need to add fields for reference market authorization details and declaration of equivalence.
UK	MHRA	Cybersecurity Requirements for SaMD	2026 (proposed)	Technical File	New cybersecurity requirements for Software as a Medical Device (SaMD) aligned with international best practices. Technical submissions for SaMD must now include cybersecurity risk assessments and lifecycle management documentation.
UK	MHRA	Predetermined Change Control Plans (PCCP)	2026 (proposed)	Technical File	Introduction of PCCPs allows pre-identification of specific change events in the submission, reducing future administrative burden. Submission wizards should add PCCP section for SaMD and AI/ML device applications.
UK	MHRA	IMDRF-Aligned Classification Rules for IVDs	2026 (proposed)	Classification	IVD classification rules aligned with IMDRF standards, replacing the current Annex II/III MDD-derived approach. This may reclassify certain IVDs and affect the applicable submission pathway and dossier scope.
UK	MHRA	Class IIb/III Custom-Made Device QMS Requirement	2026 (proposed)	Technical File	Class IIb and Class III custom-made implantable devices will require UK Approved Body QMS certification, stronger technical documentation, enhanced traceability, and formal design controls. New wizard section needed for CMDs.
UK	MHRA	Electronic Instructions for Use (eIFU) Expansion	2026 (proposed)	Labeling	Regulations expand the permitted use of electronic IFU, reducing reliance on paper-based instructions. Submission wizards must accommodate eIFU declarations and reference document URLs as part of labeling submissions.

ASIA-PACIFIC Japan · China · Australia · Singapore

Country	Authority	Update / Change	Effective Date	Impact Area	Description
Japan	PMDA / MHLW	eCTD v4.0 — Sole Mandatory Submission Format	Apr 1, 2026	Portal/eSubmission	Japan is the first major regulatory authority to mandate eCTD v4.0 for all new medical device applications. eCTD v3.2.2 no longer accepted for new dossiers. v4.0 features a single XML exchange message encompassing Modules 1–5 with STED format integrated into Modules 2–5.
Japan	PMDA / MHLW	eCTD v4.0 — Japan-Specific Module 1 Requirements	Apr 1, 2026	Portal/eSubmission Technical File	All submissions must include Japan-specific Module 1 content in Japanese (or with Japanese translation). STED (Summary of Technical Documentation) mapped into CTD Modules 2–5. Existing v3.2.2 dossiers may continue in that format for subsequent sequences only.
Japan	PMDA / MHLW	JIS T 0601-1-2:2023 EMC Compliance Mandatory	Feb 2026	Technical File	Full compliance with updated JIS T 0601-1-2:2023 electromagnetic compatibility standard required by February 2026. Technical submissions must include updated EMC test data per the new standard.
China	NMPA	Revised GMP (Announcement No. 107/2025) — In Effect Nov 2026	Nov 1, 2026	Technical File	Revised Medical Device GMP adds three new chapters: quality risk management, comprehensive quality assurance, and digital intelligence in manufacturing. All manufacturers must demonstrate compliance; QMS documentation in technical dossiers must be updated accordingly.
China	NMPA	Classification Change Management (Announcement No. 52/2026)	Jun 1, 2026	Classification	Standardized management of classification changes across Class I, II, and III devices. Unified procedural framework for all reclassification outcomes (registered devices, pending applications, IVD reagents). Submission strategy affected for any device under reclassification review.
China	NMPA	2026 Guidelines Revisions Plan (56 Class III / 219 Class II Devices)	Apr 27, 2026	Technical File Clinical Evidence	NMPA published revisions plan impacting 275 device categories. Changes affect type testing requirements, non-clinical and clinical evaluation methodology, and regulatory submission content. Submission wizards must reflect updated dossier requirements for each affected device category.
China	NMPA	15 Revised Industry Standards — In Effect Nov 2026	Nov 1, 2026	Technical File	Fifteen revised industry standards take effect November 1, 2026 (alongside GMP readiness). Manufacturers must plan for parallel compliance with both GMP and standards updates in technical documentation.
Australia	TGA	UDI Mandatory — Class IIb & III Devices	Jul 1, 2026	UDI Labeling	Sponsors of Class IIb and Class III devices must: (1) place UDI carrier on device labels, and (2) submit UDI-DI data to the Australian UDI Database (AusUDID). Direct marking required from Jan 2028 (Class III) and Jan 2029 (Class IIb).
Australia	TGA	AI-Enabled SaMD Guidance — Updated Classification & Evidence	Feb 5, 2026	Classification Clinical Evidence	Updated TGA guidance clarifies AI-enabled software classification, evidence generation, and lifecycle management requirements. AI-enabled software must be listed on the ARTG. Submissions for SaMD must include updated classification rationale and evidence packages per new guidance.
Australia	TGA	Mandatory Adverse Event Reporting by Healthcare Facilities	Mar 21, 2026	Transition/Deadline	Stage 1: Public/private hospitals must legally report adverse events for Class III and Class 4 IVD devices resulting in death or serious health deterioration. Stage 2 (April 2028) extends to medium-risk devices. Impacts PMS requirements in registration submissions.
Singapore	HSA	GN-15 Revision 13 — Updated Registration Guidance	Mar 2026	Portal/eSubmission	HSA Guidance GN-15 Rev. 13 clarifies mandatory registration requirements under the Health Products Act. Emphasizes mandatory use of the HSA SHARE Platform for all electronic applications. Updated risk classification criteria and conformity assessment pathways.
Singapore	HSA	QMS Audit Report Required for Dealer License Applications	Apr 1, 2026	Technical File	Medical device dealer license applicants must now submit their latest QMS audit reports alongside ISO certificates. Submission wizard must include QMS audit report upload as a new mandatory document for dealer licence applications.
Singapore	HSA	COVID-19 IVD Reclassification (Class D → Class C)	Jun 2, 2026	Classification	COVID-19 IVDs reclassified from Class D to Class C. Submission requirements and review timelines change accordingly. Devices in-market under Class D registration need to be updated; new submissions use Class C pathway.
Singapore	HSA	GL-04 — Revised Software Medical Device Guidance	Dec 2025 (active 2026)	Technical File Classification	Revised GL-04 covers entire software lifecycle, aligns definitions with international standards, clarifies cybersecurity and machine learning requirements, and introduces a Change Management Program (CMP) for pre-approved software updates. Impacts SaMD submissions on SHARE platform.

Country	Authority	Update / Change	Effective Date	Impact Area	Description
Singapore	HSA	Regulatory Reliance with Malaysia MDA	Mar 1, 2026	Transition/Deadline	Formalized reliance arrangement allows Class B, C, and D devices registered with Malaysia's MDA (full conformity assessment) to benefit from streamlined registration in Singapore, provided identical labelled use in both countries. New submission pathway option in wizard.



ASIA-PACIFIC (CONT.) Malaysia · South Korea · India

Country	Authority	Update / Change	Effective Date	Impact Area	Description
Malaysia	MDA	Mandatory Registration Number on Device Labels	Jul 31, 2026	Labeling	7th edition labeling guidance mandates all registered medical devices display their Malaysian registration number on the label by July 31, 2026. More rigorous framework for electronic Instructions for Use (e-IFU) also introduced.
Malaysia	MDA	Aesthetic Devices Designated as Medical Devices	Jun 1, 2026	Classification	Designated Medical Devices Order 2026 brings medical lasers, HIFU systems, and liposuction equipment under MDA Act 737. These devices now require full MDA registration. New device category to be added to wizard classification workflows.
Malaysia	MDA	Regulatory Reliance with Singapore HSA	Mar 1, 2026	Transition/Deadline	Devices registered on Singapore's SMDR (Class B, C, D with full conformity assessment) may use the Verification Route for streamlined Malaysian registration. New submission pathway option impacting wizard structure for Singapore-approved devices.
Malaysia	MDA	Class A Device Fee Increase	Jan 1, 2026	Transition/Deadline	Application fee for Class A devices increased from RM 100 to RM 500; new registration fee of RM 750 introduced. Submission wizards should display updated fee schedules for Class A device registrations in Malaysia.
Malaysia	MDA	Change Management Guidance (MDA/GD/0072 — 1st Edition)	2026	Technical File	New guidance on change management for registered medical devices published. Will supersede MDA/GD/0020 after MedCAST 3.0 launch. Important for post-approval change submissions through the MedCAST portal.
S. Korea	MFDS	Medical Device Act Amendments — QMS & Supply Chain Records	Jul 1, 2026	Technical File Transition/Deadline	Amendments formalize the QMS Conformity Recognition Scheme and introduce mandatory supply chain record-keeping for manufacturers, importers, distributors, and sellers. End-to-end traceability from manufacturing to point-of-use required. QMS section of submission wizards must capture conformity recognition data.
S. Korea	MFDS	MFDS Notice 2026-6 — Revised Medical Device Approval Regulations	May 2026	Technical File Portal/eSubmission	Comprehensive revision of the Regulation on Medical Device Approval, Notification, and Review (Notice 2026-6) aligned with international standards. Impacts how submissions are prepared, technical files documented, and compliance maintained. Submission Builder wizards must align to revised review requirements.
S. Korea	MFDS	Revised Regulations for Digital Medical Products & AI (Notice 2026-4)	Jan 2026	Classification Technical File	Revised classification and designation regulations for digital medical products. AI Basic Act in effect. Heightened obligations for AI-enabled digital medical products, including risk management plans and human oversight protocols. New AI/digital section required in submission wizards.
India	CDSCO	Mandatory Import Licensing via SUGAM Portal	2026	Portal/eSubmission	All imported medical devices, regardless of risk class, now require an official import license from CDSCO via the SUGAM portal before market entry. Replaces previous voluntary registration framework. Foreign manufacturers must appoint an Indian Authorized Agent (IAA). Full electronic submission process.
India	CDSCO	SaMD Framework — Four-Tier Risk Classification Formalized	2026	Classification Technical File	AI-powered diagnostic, treatment, and monitoring software formally classified as medical devices under a new four-tier risk framework. Cybersecurity documentation, algorithm transparency, validation datasets, and bias mitigation now required in SaMD submissions.
India	CDSCO	Updated Labeling & Testing Requirements (MDR Amendment 2026)	2026	Labeling	2026 CDSCO Medical Device Amendment Rules introduce new labeling requirements and updated testing fees. Incomplete labeling drafts are a leading cause of application returns. Submission wizard must validate all mandatory labeling elements before submission.
India	CDSCO	Risk-Based QMS Audits (ISO 13485 + ISO 14971 Focus)	2026	Technical File Clinical Evidence	Shift to risk-based on-site audits moving away from purely document reviews. Class C and D devices face full audits; Class A and B face sampling audits. ISO 13485 and ISO 14971 compliance with full traceability required across design, production, and PMS documentation.



MIDDLE EAST & AFRICA

Saudi Arabia · UAE · South Africa

Country	Authority	Update / Change	Effective Date	Impact Area	Description
Saudi Arabia	SFDA	MDMA2 (Saudi Route) — Exclusive Registration Pathway	2026 (enforced)	Portal/eSubmission Technical File	MDMA2 (Saudi Route) with full Technical File Assessment is the sole pathway for all device classes. Earlier GHTF route and MDNR listing discontinued. All submissions via GHAD e-Service system. Comprehensive technical file required (mirrors EU MDR scope), including labeling in Arabic and English, ISO 13485 cert, and clinical data.
Saudi Arabia	SFDA	EU MDR CE Certificates Required (Not MDD)	2026 (enforced)	Technical File Transition/Deadline	SFDA now requires CE certificates issued under EU MDR 2017/745. MDD-based certificates generally no longer accepted for SFDA submissions. Manufacturers must confirm EU MDR certification status before preparing SFDA dossiers.
Saudi Arabia	SFDA	Bilingual Labeling — Arabic & English Mandatory	2026 (enforced)	Labeling	All medical device labels and IFUs must be in both Arabic and English for SFDA registration. Submission wizards must include a bilingual labeling compliance checklist as a mandatory step in SFDA applications.
UAE	EDE (formerly MOHAP)	Authority Shift: EDE Replaces MOHAP as Sole Regulator	Early 2026	Portal/eSubmission	Emirates Drug Establishment (EDE) now assumes full responsibility for all medical device services previously under MOHAP. All new and ongoing submissions exclusively through EDE portal at www.ede.gov.ae . MOHAP retains only pharmacy jurisdiction. Critical system change for all UAE submissions.
UAE	EDE	EDE Anti-Monopoly Policy — Multi-Agent Requirement	Feb 2026	Portal/eSubmission	EDE introduced a requirement for companies to appoint more than one agent per medical product in the UAE. Breaks the previous single-distributor monopoly model. Impacts the Local Authorized Representative (LAR) fields in submission wizards for UAE registrations.
UAE	EDE	Enhanced PMS — Biannual PSURs for High-Risk Devices	2026	Transition/Deadline Technical File	Biannual Periodic Safety Update Reports (PSURs) mandatory for Class III/IV devices. Adverse event reporting within 10–30 days (by severity). Field Safety Corrective Actions (FSCA) must be reported to EDE before implementation. PMS plan required in initial submission.
UAE	EDE	Manufacturing Site Registration Prerequisite	2026 (enforced)	Technical File	Manufacturing facility must be registered with EDE before product applications can be submitted. Requires current ISO 13485 certificate, manufacturing license from country of origin, and GMP compliance evidence. Site registration is a sequential prerequisite in the UAE submission workflow.
S. Africa	SAHPRA	ISO 13485:2016 Mandatory for Existing License Holders	Apr 1, 2026	Technical File Transition/Deadline	All existing SAHPRA establishment license holders must have ISO 13485:2016 certificates available for verification from April 1, 2026. SAHPRA may request proof during audits or vigilance activities. For renewals, ISO 13485 certificate must accompany renewal application. Mandatory prerequisite for new applications from April 2028.
S. Africa	SAHPRA	Medical Devices Reliance Guideline (SAHPGL-MD-22)	Feb 2026	Transition/Deadline Technical File	Formalized reliance pathways from FDA, EU MDR/IVDR, TGA, PMDA, Health Canada, ANVISA, and WHO Prequalification for IVDs. Submission wizards must support reliance pathway selection and reference market authorization documentation fields for SAHPRA applications.
S. Africa	SAHPRA	Licensing Requirements for Outsourced Activities (MD02-2026/27)	Apr 10, 2026	Technical File	New guideline MD02-2026/27 on licensing requirements for outsourced or contracted activities for medical device establishments. Impacts manufacturers using contract manufacturers or third-party distributors in South Africa. Submission dossiers must address outsourced activity documentation.
S. Africa	SAHPRA	e-IFU Regulatory Requirements (MD03-2026/27)	May 8, 2026	Labeling	New SAHPRA regulatory requirements for electronic Instructions for Use (e-IFU) published May 2026. Defines when e-IFU is permitted and what conditions must be met. Submission wizards for SAHPRA must include e-IFU compliance declarations.
S. Africa	SAHPRA	Certificate of Free Sale Guidance Updated (SAHPGL-MD-21)	Mar 2026	Technical File	Updated CFS guideline confirms that a CFS is required confirming devices are legally sold/distributed without restriction in South Africa. Foreign manufacturers must include a valid CFS from their country of manufacture in the SAHPRA submission dossier.



INSIGHTS Key Observations & Strategic Implications

Portals & eSubmission Systems Are Transforming

2026 sees five major portal changes: FDA eSTAR v7.0 mandatory (Aug), Japan PMDA mandating eCTD v4.0 (Apr), Canada's REP/CESG as the only accepted channel (Jan), EU EUDAMED four modules mandatory (May), and UAE EDE replacing MOHAP entirely. Submission Builder wizards must map to each new portal API and document structure.

UDI Is Becoming Universal in 2026

A major wave of UDI enforcement: EU EUDAMED UDI module mandatory (May), Australia Class IIb/III UDI on labels and in AusUDID (Jul), Brazil SIUD data transmission mandatory (Mar), and UK MHRA proposing universal UDI. Submission wizards must treat UDI as a core mandatory field, not optional, across most major markets.

AI/SaMD Creates New Mandatory Wizard Sections

At least six markets now have formal AI/SaMD frameworks active or proposed in 2026: India (four-tier risk), South Korea (AI Basic Act), Singapore (GL-04 + AIHGle 2.0), USA (Human Factors integration), Australia (updated SaMD guidance), and Canada (AI/ML lifecycle guidance). Wizards need a dedicated AI/SaMD pathway with cybersecurity, algorithm transparency, and CMP fields.

Regulatory Reliance Networks Expanding

Multiple new bilateral and multilateral reliance frameworks launched in 2026: Malaysia–Singapore MDA/HSA (Mar), SAHPRA formalized reliance guideline (Feb), Mexico expanded equivalency route, COFEPRIS aligned with 11+ authorities, Brazil IN 290 for Class III/IV, and Canada adopting IMDRF ToC. Submission wizards should offer a "reliance pathway" option with reference market selection fields.

Technical File Complexity Increasing

China's revised GMP (Nov), NMPA's 275-device guidelines revisions plan, South Korea's MFDS Notice 2026-6, and CDSCO's risk-based audit shift all signal increasing expectations for technical documentation completeness and traceability. Submission wizards should provide built-in checklists aligned to each market's current dossier requirements.

Labeling Requirements Tightening Globally

Malaysia (mandatory registration number Jul 31), Mexico (NOM-137 final May), SAHPRA (e-IFU MD03-2026/27), UK MHRA (expanded eIFU), Saudi Arabia (bilingual Arabic/English mandatory), India (MDR 2026 labeling amendments) — all active in 2026. Labeling module in submission wizards must be market-specific with mandatory field validation for each jurisdiction.

SOURCES & REFERENCES

- FDA — eSTAR v7.0 Release: [emergobyul.com / fda.gov](https://www.fda.gov/emergobyul) (June 2026)
- FDA — Human Factors Guidance: [exponent.com](https://www.fda.gov/exponent) (Aug 2026)
- EU MDR — EUDAMED Mandatory: [europa.eu / intertek.com](https://www.europa.eu/intertek) (May 2026)
- EU MDR — EUDAMED Legacy Deadline: [medenvoyglobal.com](https://www.medenvoyglobal.com) (Nov 2026)
- MHRA — Draft Amendment Regulations 2026: [dacbeachcroft.com / nsf.org](https://www.dacbeachcroft.com)
- MHRA — UDI & Reliance Pathway: [patientguard.com / lw.com](https://www.patientguard.com)
- Health Canada — REP/CESG Mandatory: [mdlaw.eu / medenvoyglobal.com](https://www.mdaweb.ca/medenvoyglobal)
- Health Canada — Guidance v5 & IMDRF ToC: [nsf.org / complifegroup.com](https://www.nsf.org/complifegroup)
- Health Canada — MDEL Phase 2 (SOR/2026-110): [gazette.gc.ca / torys.com](https://www.gazette.gc.ca/torys.com)
- ANVISA — UDI SIUD NI 426/2026: [emergobyul.com / brisa.com.br](https://www.emergobyul.com)
- ANVISA — 2026-2027 Agenda: [emergobyul.com / proregulations.com](https://www.emergobyul.com/proregulations)
- COFEPRIS — NOM-137-SSA1-2025 Labeling: [emergobyul.com](https://www.emergobyul.com) (May 2026)
- COFEPRIS — Equivalency Route: [mavenrs.com / pureglobal.com](https://www.mavenrs.com)
- PMDA — eCTD v4.0 Mandate: [meddeviceguide.com / freyrsolutions.com](https://www.meddeviceguide.com)
- NMPA — GMP Announcement No. 107/2025: [emergobyul.com](https://www.emergobyul.com)
- NMPA — Classification Changes No. 52/2026: [complifegroup.com](https://www.complifegroup.com)

- NMPA — 2026 Guidelines Revisions Plan: [chinameddevice.com](https://www.chinameddevice.com)
- TGA — UDI Class IIb/III Mandatory: [tga.gov.au / reedtech.com](https://www.tga.gov.au/reedtech)
- TGA — AI SaMD Guidance Feb 2026: [regask.com / pureglobal.com](https://www.regask.com/pureglobal)
- HSA Singapore — GN-15 Rev. 13: [qualtechs.com / bakermckenzie.com](https://www.qualtechs.com/bakermckenzie)
- HSA Singapore — GL-04 Revised: [morulaa.com / andamanmed.com](https://www.morulaa.com/andamanmed)
- MDA Malaysia — Labeling 7th Edition: [complifegroup.com](https://www.complifegroup.com) (Mar 2026)
- MDA Malaysia — Designated Medical Devices Order 2026: [pureglobal.com](https://www.pureglobal.com)
- MFDS Korea — Act Amendments Jul 2026: [qualtechs.com](https://www.qualtechs.com)
- MFDS Korea — Notice 2026-6: [regdesk.co](https://www.regdesk.co)
- CDSCO India — Import Licensing SUGAM: [healthcareguys.com](https://www.healthcareguys.com)
- CDSCO India — SaMD Framework 2026: [digitalhealthnews.com](https://www.digitalhealthnews.com)
- SFDA Saudi Arabia — MDMA2 Enforcement: [gulfabsupplies.com / omcmedical.com](https://www.gulfabsupplies.com/omcmedical)
- EDE UAE — Authority Transfer from MOHAP: [regdesk.co / meddeviceguide.com](https://www.regdesk.co/meddeviceguide)
- SAHPRA — ISO 13485 Mandate Apr 2026: [regdesk.co / sahpra.org.za](https://www.regdesk.co/sahpra.org.za)
- SAHPRA — Reliance Guideline SAHPGL-MD-22: [sahpra.org.za](https://www.sahpra.org.za) (Feb 2026)