



SUBMISSION BUILDER INTELLIGENCE

Regulatory Update Report 2025–2026

Impact Assessment for Submission Builder Wizards

PERIOD COVERED
2025 – 2026

MARKETS ASSESSED
40 Countries

PRODUCT SCOPE
MD + IVD — New Registration

REPORT DATE
July 2026

Executive Summary

5

P0 — Release Blockers

7

P1 — Mandatory Changes

6

P2 — Conditional Updates

8+

Watchlist Items

Scope: 40 wizard markets assessed · Period: 2025–2026 (published or effective) · Product type: Medical Devices + IVDs · Lifecycle stage: New registration / marketing authorization only.

CRITICAL FINDINGS — IMMEDIATE ACTION REQUIRED

Priority	Market	Change	Deadline
P0	USA	eSTAR v7.0 — version-locked artifacts for all 510(k)/PMA/De Novo pathways	2026 (enforced)
P0	Canada	REP mandatory XML submission — Class II–IV new licences	1 Apr 2026
P0	EU	EUDAMED 4 modules mandatory — all new MDR/IVDR placements	28 May 2026
P0	UK	GB vs. NI routing split — separate MHRA DORS vs. EUDAMED branches	28 May 2026
P0	Switzerland	swissdamed mandatory — Swiss-specific dataset, CHRN required	31 Dec 2026

KEY P1 CHANGES REQUIRING DEVELOPMENT

Market	Change	Scope
Australia	UDI mandatory for Class III/IIb — AusUDID post-approval 30-day link task	MD only
China	NMPA classification catalogue adjustment — 31-item table, RF → Class III from Apr 2026	MD + IVD
Egypt	UDI Guideline v02/2026 — structured Egyptian UDI block with Arabic fields	MD + IVD
Indonesia	Halal mandatory for Class A MDs from 18 Oct 2026	MD only
Brazil	SIUD/UDI class-phased — 1 Mar 2026 system launch ≠ universal mandate	MD + IVD
South Africa	Reliance pathway + e-IFU conditional branches	MD + IVD
Saudi Arabia	MDMA2 (Saudi Route) + GHAD mandatory + UDI full enforcement + MDS-G-028 bundling	MD + IVD

MAJOR EXCLUSIONS FROM MAIN REGISTER

The following items were researched and excluded: **UAE MOHAP – EDA transfer** (no official instrument found — remains Watchlist); **FDA electronic labeling NPRM** (not final rule); **MHRA post-Brexit reliance pathway** (still in consultation); **Brazil UDI universal mandate from 1 March 2026** (misread of SIUD system launch — obligation is class-phased per RDC 591/2021).

P0 Release Blockers — Existing Wizard Cannot Produce Acceptable Submission

USA — eSTAR v7.0 P0

FDA's eSTAR v7.0 replaces all prior versions for 510(k), De Novo, and PMA submissions. Version-locked field IDs and separate artifacts per pathway; June 2026 human factors additions in scope. Existing wizards generating v6.x output will be rejected.

REQUIRED WIZARD CHANGES

- Maintain separate source artifacts per pathway: nIVD 510(k), IVD 510(k), PMA, De Novo — each version-locked to v7.0 field IDs
- Lock all form field identifiers, JS conditions, and attachment anchors to v7.0 template
- Add submission-state rule: in-progress submissions continue in v6.x; new submissions default to v7.0
- Add June 2026 human factors section: HF data fields, use-error analysis, summative/formative study references
- Validate generated output against FDA eSTAR v7.0 acceptance schema before export

ACCEPTANCE TESTS (MANDATORY)

- Golden-path export for each pathway (nIVD 510k, IVD 510k, PMA) validates against v7.0 schema
- Round-trip XML: export → re-import → same data, no field-ID drift
- Failure: v6.x field ID in export triggers rejection flag

Scope: MD + IVD **Effective:** 2026 (FDA enforced) **Source:** FDA eSTAR Program — [fda.gov/medical-devices](https://www.fda.gov/medical-devices) **Confidence:** HIGH

Canada — REP (Regulatory Enrolment Process) Mandatory P0

Health Canada REP becomes mandatory 1 April 2026 for Class II–IV new medical device licence applications. Applications not submitted via REP XML structure will not be accepted. Class I, MDEL, investigational, and Special Access are excluded from REP scope.

REQUIRED WIZARD CHANGES

- Replace form/PDF output with structured REP XML objects: Company CO, dossier, regulatory transaction
- Make prerequisites explicit: Company CO object must be finalized before dossier object can proceed
- Capture IMDRF Table of Contents dossier structure; validate all mandatory sections present
- Generate CESC-ready package (cover letter, data elements, structured attachments)
- Scope gate: Class I / MDEL / investigational → exclude from REP flow, continue legacy path
- Migration rule: applications initiated before 1 Apr 2026 in legacy format — do NOT silently convert

ACCEPTANCE TESTS (MANDATORY)

- Valid XML for each REP object against current Health Canada schema
- Failure when Company CO missing or IDs inconsistent across objects
- Class I application correctly excluded from REP path

Scope: MD (Class II–IV) **Effective:** 1 Apr 2026 **Source:** Health Canada — REP for Medical Devices **Confidence:** HIGH

EU — EUDAMED Four Modules Mandatory P0

Regulation (EU) 2024/1860 makes EUDAMED's first four modules mandatory from 28 May 2026 for all new MDR/IVDR devices placed on the EU market. Sequential actor registration, UDI-DI/device record, and packaging hierarchy records must be completed before market placement.

REQUIRED WIZARD CHANGES

- Sequential module flow: Actor Registration (SRN) → Basic UDI-DI → UDI-DI/Device record → Packaging records
- SRN prerequisite gate: manufacturer and authorized rep SRNs must exist before device record creation
- Apply current EUDAMED DTX/XSD enumerations (version-locked to current official schema at export time)
- Block submission routing until all four EUDAMED modules are marked complete
- Date-triggered rule: remove pre-EUDAMED legacy EU registration flow for new submissions after 28 May 2026

Scope: MD + IVD **Effective:** 28 May 2026 **Source:** Regulation (EU) 2024/1860 · EC EUDAMED portal **Confidence:** HIGH

UK — GB vs. NI Market Routing Split P0

From 28 May 2026, devices targeting Great Britain (MHRA DORS) and Northern Ireland (EU MDR/IVDR via EUDAMED) must be handled as separate, independent registration branches. Duplicate NI-via-MHRA registration is removed for non-custom devices post May 2026.

REQUIRED WIZARD CHANGES

- Replace single UK output with explicit target-market branch: GB (MHRA DORS) vs. NI (EUDAMED MDR/IVDR)
- GB branch: collect GMDN code (mandatory for GB DORS), MHRA-specific responsible person identity
- NI branch: route to EUDAMED flow (shares EU P0 logic above), EU-authorized representative identity
- Capture responsible person identity per branch — do NOT reuse GB person for NI
- Date-triggered removal: legacy combined UK registration flow disabled for new submissions after 28 May 2026

ACCEPTANCE TESTS (MANDATORY)

- GB only → MHRA DORS output with GMDN; no EUDAMED data
- NI only → EUDAMED-ready output; no MHRA DORS data
- Both selected → two complete, independent outputs with distinct representatives

Scope: MD + IVD **Effective:** 28 May 2026 **Source:** MHRA device registration guidance **Confidence:** HIGH

Switzerland — swissdamed Mandatory P0

Swissmedic's swissdamed database becomes mandatory by 31 December 2026. The Swiss dataset is NOT a copy of EUDAMED — Swiss-specific data elements are required. CHRN (Swiss registration number) applies where applicable.

REQUIRED WIZARD CHANGES

- Add Switzerland-specific data collection branch (separate from EU EUDAMED flow)
- Collect Swiss-specific dataset: CHRN (where applicable), Swissmedic authorization number, Swiss authorized representative
- Current-law vs. legacy branching: route by whether device is under current Swiss MedDO or legacy law
- Validate swissdamed required fields against current Swissmedic schema before export
- Date gate: flag all Swiss new registrations initiated after 31 Dec 2026 as swissdamed-required

Scope: MD + IVD **Effective:** 31 Dec 2026 (transition deadline) **Source:** Swissmedic — swissdamed guidance **Confidence:** HIGH

P1 Mandatory Conditional Logic — Development Required

Australia — UDI for Class III and Class IIb P1

TGA UDI compliance timeframes v2.1 (June 2026) extend mandatory UDI compliance to Class III and IIb medical devices. IVDs are excluded from the 2026 UDI scope. A post-approval task to link AusUDID record within 30 days of first supply is required.

REQUIRED WIZARD CHANGES

- Add UDI applicability rule: country=AUS AND device_class IN (IIb, III) AND date ≥ 2026 → UDI branch required
- Collect: issuing agency (GS1/HIBCC/ICCBBA), Primary DI, Unit of Use DI (when base qty > 1), package hierarchy, PI types (LOT/serial/expiry/mfg date)
- Add direct-marking applicability/exemption field with evidence upload
- Create post-approval task: link AusUDID record within 30 days of first supply; block case closure until linked
- IVD gate: AUS + IVD → UDI branch NOT triggered in 2026 scope

Scope: MD only (Class III + IIb) **Effective:** 2026 (TGA UDI timeframes v2.1) **Source:** TGA — UDI Compliance Timeframes v2.1 **Confidence:** HIGH

China — NMPA Classification Catalogue Adjustment P1

NMPA Announcement 2025 No. 132 adjusts classification for 31 device items effective 4 January 2026. RF therapeutic/skin-treatment devices are reclassified to Class III effective 1 April 2026. Class recalculation, authority routing, and dossier path must be updated.

REQUIRED WIZARD CHANGES

- Load official 31-item adjustment table as controlled classification source (version-stamped: Announcement 2025 No. 132)
- On product match: recalculate class, responsible authority (NMPA vs. provincial), dossier route, fee/timeline
- Add RF device hard gate: RF therapeutic/skin-treatment → Class III mandatory from 1 April 2026
- Store classification-rule version and effective date on each case
- Alert when product name/code matches an adjusted entry in a draft case started before effective date
- Prevent selection of superseded class without documented regulator decision

Scope: MD + IVD **Effective:** 4 Jan 2026 (RF devices: 1 Apr 2026) **Source:** NMPA Announcement 2025 No. 132 **Confidence:** HIGH

Egypt — UDI Guideline v02/2026 P1

EDA's UDI Guideline v02/2026 introduces a structured Egyptian UDI block required for all registered devices. Arabic-language fields are mandatory for lay-use devices. Label carrier enforcement date is being confirmed.

REQUIRED WIZARD CHANGES

- Add Egyptian UDI block: Primary DI, UDI-PIs (LOT/serial/expiry/mfg date as applicable), GMDN code, device class
- Add boolean fields: sterile Y/N, reusable Y/N, MRI-compatible Y/N, latex-containing Y/N
- For lay-use devices: add Arabic brand name + Arabic device description (mandatory)
- Applicability rule: all devices registered in Egypt (MD + IVD) → UDI block required

Scope: MD + IVD **Effective:** 2026 (enforcement date TBC) **Source:** EDA — Regulatory Guideline on UDI for Medical Devices v02/2026 **Confidence:** HIGH

Indonesia — Halal Mandatory for Class A Medical Devices P1

Indonesia Government Regulation No. 42 of 2024 makes halal certification mandatory for risk Class A medical devices effective 18 October 2026. An exception pathway exists with documented legal basis. IVDs are not covered under the same rule.

REQUIRED WIZARD CHANGES

- Trigger halal branch only when: country=Indonesia AND device_class=A AND placement_date ≥ 18 Oct 2026
- Collect: material origin, animal-derived/prohibited-material status, manufacturing-process evidence
- Branch A (halal): certificate number, issuing body (BPJPH-approved), validity date, scope, label evidence
- Branch B (exception): legal basis for exception, required non-halal information/markings documentation
- Gate: Class A determination + material origin must both be confirmed before halal branch triggers

ACCEPTANCE TESTS

- Indonesia Class A, date ≥ Oct 2026 → halal branch appears
- Indonesia non-Class A → halal branch absent
- Exception path → certificate fields hidden, legal basis field required

Scope: MD only (Class A) **Effective:** 18 Oct 2026 **Source:** BPJPH · Indonesia Gov. Reg. No. 42/2024 · MoH Reg. No. 3/2024 **Confidence:** HIGH

Brazil — SIUD/UDI Class-Phased Rollout P1

ANVISA's SIUD system launched 1 March 2026. This is the system launch date — NOT a universal UDI mandate. Obligation per device class follows RDC 591/2021 Article 15 class-based timelines. Wizard must not treat all classes as mandatory from 1 March.

REQUIRED WIZARD CHANGES

- Add applicability rule: Brazil + device class → look up mandatory date per RDC 591/2021 Art. 15 class schedule
- Collect structured UDI dataset: Primary DI, UDI-PIs, device class, package hierarchy
- Add SIUD-to-ANVISA record linkage step; support manual and M2M upload confirmation
- ⚠ Do NOT set 1 March 2026 as universal mandatory date — use per-class effective date

Scope: MD + IVD (class-phased) **Effective:** Class-based per RDC 591/2021 Art. 15 **Source:** ANVISA — SIUD/UDI · RDC 591/2021 **Confidence:** HIGH

South Africa — Reliance Pathway + e-IFU Conditional Branches P1

SAHPRA's reliance guideline and e-IFU requirements are operational in 2026, adding two conditional branches to the South Africa wizard. Both are optional pathways — NOT universal requirements for all applications.

REQUIRED WIZARD CHANGES

- Add optional reliance branch: reference authority (FDA/EMA/TGA etc.), foreign authorization number, equivalence declaration/evidence upload
- Add conditional e-IFU branch: URL/mechanism, document version, printed copy availability statement
- Both branches must be conditional — only appear when applicant selects reliance or e-IFU pathway
- Routing: standard ZAF application path remains unchanged for non-reliance applications

Scope: MD + IVD **Effective:** 2026 **Source:** SAHPRA — Medical Devices Reliance Guideline · SAHPRA e-IFU requirements **Confidence:** HIGH

Saudi Arabia — MDMA2 + GHAD + UDI + MDS-G-028 Bundling P1

Multiple SFDA changes effective 2025–2026: MDMA2 (Saudi Route) is now the sole registration pathway requiring full Technical File Assessment for all classes. GHAD system is mandatory for all submissions. UDI is fully operational across all classes. New MDS-G-028 guidance (effective 3 May 2026) changes device bundling rules affecting multi-device MDMA applications. GHTF-leveraged approvals as sole basis for registration are no longer accepted.

REQUIRED WIZARD CHANGES

- Route all SAU registrations via MDMA2 (Saudi Route) — remove GHTF-leveraged shortcut as standalone path
- All submissions via e-GHAD portal — add GHAD application number field; wizard output must be GHAD-compatible
- Add UDI block for all SAU device classes: Primary DI, UDI-PIs, Saudi-DI record linkage
- UDI label requirements: both human-readable and machine-readable formats on primary label and all packaging levels
- MDS-G-028 bundling gate (from 3 May 2026): multiple devices in single MDMA must comply with new bundling criteria — add bundling eligibility check to SAU wizard
- Updated classification guidance (applicable Nov 2025): load current SFDA classification definitions including SaMD/AI/combination product categories

Scope: MD + IVD **Effective:** Various — MDMA2 2025; MDS-G-028 3 May 2026; UDI fully operational 2026 **Source:** SFDA — MDMA2 guidance · GHAD portal · UDI Requirements PDF · MDS-G-028

Confidence: MEDIUM (secondary regulatory sources; SFDA portal not directly fetched)

P2 Conditional / Limited Updates

USA — QMSR Terminology Update P2

FDA's Quality Management System Regulation (QMSR) replaced the Quality System Regulation (QSR) with enforcement effective February 2026. Wizard text and export labels must use QMSR/ISO 13485:2016 terminology. No new mandatory certification fields are required — existing ISO 13485 cert data collection is sufficient.

REQUIRED WIZARD CHANGES

- Replace all QSR/QSIT labels and help text with QMSR terminology throughout wizard
- Update applicability prompts: reference ISO 13485:2016 + FDA-specific QMSR requirements
- Do NOT add mandatory ISO 13485 cert field — existing data collection is adequate
- Text audit: search for "QSR", "QSIT" in all wizard labels and export labels; replace with QMSR equivalents

Scope: MD + IVD **Effective:** Feb 2026 (grace period ended) **Source:** 21 CFR Part 820 revised **Confidence:** HIGH

South Korea — Digital Medical Device GMP Track P2

MFDS published a new GMP chapter specifically for Digital Medical Devices (SaMD) on 11 February 2026. This creates a distinct registration and GMP compliance track separate from hardware MD and IVD, with new software-specific documentation requirements.

REQUIRED WIZARD CHANGES

- Add device type routing at Korea wizard start: "Digital Medical Device (SaMD)" as distinct type
- If Digital MD: add fields for software description, version control method, cybersecurity approach
- Route to Digital MD GMP track — separate from standard hardware MD track
- IVD: remains under separate IVD Act — no change from current IVD routing

Scope: MD (SaMD) **Effective:** 11 Feb 2026 **Source:** MFDS — Medical Device GMP Regulations (English) · mfds.go.kr/eng/brd/m_40/view.do?seq=72638 **Confidence:** HIGH

India — CDSCO SUGAM e-Submission Expansion + Authorized Agent

P2

CDSCO's SUGAM portal continues expanding as the mandatory electronic submission platform for Class C/D devices (and progressively Class A/B). Foreign manufacturers must appoint an Indian Authorized Agent. IVD classification under MDR 2017 Schedule III applies separate criteria from hardware MDs.

REQUIRED WIZARD CHANGES

- Add "SUGAM Application Number" field (auto-populated or manually entered after portal submission)
- Add India Authorized Agent section: name, CDSCO registration number, contact details
- India classification routing: map to MDR 2017 risk classes A/B/C/D — not GHTF classes
- IVD sub-classification: add IVD-specific criteria screen per MDR 2017 Schedule III (Class C/D require performance evaluation data)

Scope: MD + IVD **Effective:** Ongoing (Class C/D confirmed; Class A/B phase-in) **Source:** CDSCO — MDR 2017 · SUGAM portal

Confidence: MEDIUM (site inaccessible in research session; well-established regulatory knowledge)

Global Implementation Matrix — All Confirmed Changes

All confirmed changes. Priority → Market → Scope → Key Change → Deadline. Items with MEDIUM/LOW confidence are flagged.

Priority	Market	Scope	Key Change	Deadline	Confidence	SB Action
P0	USA	MD+IVD	eSTAR v7.0 — version-locked artifacts, all 510(k)/PMA/De Novo pathways	2026	HIGH	Dev required
P0	Canada	MD Class II–IV	REP mandatory XML submission — IMDRF ToC dossier, CESC package	1 Apr 2026	HIGH	Dev required
P0	EU	MD+IVD	EUDAMED 4 modules mandatory — actor → UDI-DI → device → packaging	28 May 2026	HIGH	Dev required
P0	UK	MD+IVD	GB vs. NI routing split — MHRA DORS vs. EUDAMED, GMDN for GB	28 May 2026	HIGH	Dev required
P0	Switzerland	MD+IVD	swissdamed mandatory — Swiss dataset, CHRN, current-law vs. legacy branch	31 Dec 2026	HIGH	Dev required
P1	Australia	MD (III/IIb)	UDI mandatory — AusUDID post-approval 30-day link, Primary DI + hierarchy	2026 (v2.1)	HIGH	Dev required
P1	China	MD+IVD	NMPA classification 31-item table; RF → Class III from 1 Apr 2026	4 Jan / 1 Apr 2026	HIGH	Dev required
P1	Egypt	MD+IVD	UDI v02/2026 — Egyptian UDI block, Arabic fields for lay-use devices	2026	HIGH	Dev required
P1	Indonesia	MD Class A	Halal mandatory — material origin, certificate or exception pathway	18 Oct 2026	HIGH	Dev required
P1	Brazil	MD+IVD	SIUD/UDI class-phased — not universal from 1 Mar; per RDC 591/2021 Art. 15	Class-phased	HIGH	Dev required
P1	South Africa	MD+IVD	Reliance pathway + e-IFU conditional branches (both optional)	2026	HIGH	Dev required
P1	Saudi Arabia	MD+IVD	MDMA2 sole path + GHAD mandatory + UDI all classes + MDS-G-028 bundling	Various 2025–2026	MEDIUM	Dev required
P2	USA	MD+IVD	QMSR terminology — replace QSR/QSIT labels and help text throughout wizard	Feb 2026	HIGH	Config update
P2	South Korea	MD (SaMD)	Digital MD GMP track — new routing for SaMD, software-specific doc fields	11 Feb 2026	HIGH	Dev required
P2	India	MD+IVD	SUGAM e-submission expansion + Indian Authorized Agent field + IVD sub-class screen	Ongoing 2025–2026	MEDIUM	Config update
P2	Japan	MD	UDI-J phase expansion Class II; eCTD expanding for Class III/IV submissions	From Apr 2025	MEDIUM	Monitor/Dev
Watch	UAE	MD+IVD	MOHAP → EDA transfer — no confirmed official instrument; date unverified	Unknown	LOW	Monitor only
Watch	Singapore	MD+IVD	HSA website restructure (404s on sub-pages); AMDD harmonization progression	Ongoing	MEDIUM	Monitor
Watch	Hong Kong	MD+IVD	MDR mandatory system transition — MDACS currently voluntary; announced but no confirmed date	TBC	LOW	Monitor

Watchlist — Unconfirmed / Proposed / Future Items

Items below require monitoring. None should be promoted to the main register without a confirmed official source and effective date.

Market	Change	Status	Why Not Ready	Next Milestone
UAE	MOHAP → EDA full transfer	Unverified	No official instrument or date confirmed	Monitor MOHAP/EDA portals
Singapore	AMDD harmonization Essential Principles update	In progress	Sub-pages inaccessible; no specific 2025–2026 publication confirmed	Re-check when HSA site restored
Hong Kong	MDACS mandatory transition	Proposed	Currently voluntary; no confirmed mandatory date	Monitor MDACS announcements
Japan	UDI-J Class II expansion / eCTD mandate	Ongoing rollout	Specific 2025 circular not confirmed from official source this cycle	Check PMDA/MHLW notices
Turkey	TITCK EU MDR alignment / TITUBIS updates	Partially confirmed	Specific 2025–2026 wizard-impacting changes not confirmed from official source	Check TITCK portal directly
Mexico	COFEPRIS e-submission system changes	Unknown	Official portal not accessible during research cycle	Check COFEPRIS portal
Colombia	INVIMA TRAMITES platform updates	Unknown	Not confirmed in this research cycle	Check INVIMA portal
Pakistan	DRAP new medical device rules	Unknown	Not confirmed in this research cycle	Check DRAP portal

Negative Evidence Register — Excluded Items

The following claims were investigated and excluded. They must not re-enter the main register without a new verified official source.

Claim	Reason Excluded	Verified By
UAE MOHAP → EDA full transfer Jan 2026	No official instrument found; date unverified	Research cycle 2026-07
Brazil UDI mandatory for all classes from 1 Mar 2026	Misreads SIUD system launch date; obligation is class-phased per RDC 591/2021 Art. 15	Research cycle 2026-07
MHRA post-Brexit reliance pathway finalized 2026	Still in consultation / proposal stage — not finalized	Reference markets.md
FDA electronic labeling NPRM as 2026 requirement	NPRM only — not yet a final rule	Reference markets.md
EU AI Act as 2026 wizard requirement for devices	Applicability to devices not finalized in 2026 scope	Reference markets.md

Recommended Release Sequence

Phase	Markets / Changes	Rationale	Target
Phase 1 — Immediate	USA eSTAR v7.0, Canada REP, EU EUDAMED, UK GB/NI split	All are P0 with imminent deadlines (Apr–May 2026). Existing wizards will fail without updates.	Q1–Q2 2026
Phase 2 — Near-term mandatory	Australia UDI, China classification, Egypt UDI, Indonesia Halal, Brazil SIUD, South Africa reliance, Saudi Arabia MDMA2/GHAD/UDI	All P1 with confirmed effective dates in 2026. Conditional logic changes — development scope defined.	Q2–Q3 2026
Phase 3 — Conditional updates	Switzerland swissdamed, USA QMSR text, South Korea SaMD GMP, India SUGAM, Japan UDI-J	P0 (Switzerland) has Dec 2026 deadline; P2 items are lower risk but should ship before year-end.	Q3–Q4 2026
Phase 4 — Monitor	UAE, Singapore, Hong Kong, Turkey, Mexico, Colombia, Pakistan, Vietnam, others	Watchlist items — no confirmed mandatory changes. Reassess each quarter.	Ongoing

Markets Assessed — No Confirmed Wizard Changes (2025–2026)

The following markets in the wizard inventory were assessed and no confirmed wizard-impacting changes for 2025–2026 new registration were identified at the time of research. They remain on standard monitoring: **Argentina (ARG), Bahrain (BHR), Bolivia (BOL), Chile (CHL), Colombia (COL), Ecuador (ECU), Israel (ISR), Jordan (JOR), Kuwait (KWT), Morocco (MAR), New Zealand (NZL), Pakistan (PAK), Peru (PER), Portugal (PRT, EU rules apply), Spain (ESP, EU rules apply), Taiwan (TWN), Thailand (THA), Uruguay (URY), Vietnam (VNM).**

Note: Official portal accessibility varied during this research cycle. Several markets' regulators had inaccessible pages — absence of confirmed changes does not mean no changes exist. Recommend quarterly re-check against official portals.

Scope & Methodology

CONFIRMED SCOPE

Parameter	Definition
Period covered	2025–2026
Date inclusion rule	Changes published OR effective during 2025–2026
Geographic scope	40 countries per attached wizard inventory (Application_Templates_Summary_V1.xlsx)
Product type	Medical Devices (MD) and IVDs — treated separately; MD requirements not assumed to apply to IVDs
Lifecycle stage	New product registration / marketing authorization only

INCLUSION TEST

A regulatory change was included if it: (1) is officially published (legal text, official portal notice, regulator-issued guidance), (2) is or will be effective during 2025–2026, (3) directly requires a change to questions, conditions, attachments, validation, export format, routing, or instructions in a new-registration wizard. Consultations, proposals, post-market-only changes, and general policy statements were excluded.

SOURCE HIERARCHY

- 1 — Official legal instruments (regulations, directives, government gazette publications)
- 2 — Regulator-issued guidance (official portal pages, guidance documents, circulars)
- 3 — Credible secondary sources (established regulatory consultancies, industry bodies) — labeled MEDIUM confidence
- 4 — Training knowledge — labeled MEDIUM or LOW confidence; flagged for re-verification

KNOWN LIMITATIONS

Web search quota exhausted during this research cycle (free tier: 20 searches/day). Several official portals returned 404 or connection failures during direct fetch attempts (CDSCO India, TFDA Taiwan, MDACS Hong Kong, COFEPRIS Mexico, DRAP Pakistan, TITCK Turkey). These markets are assessed as “no confirmed changes” but should be re-verified in the next cycle when portal access is restored. MEDIUM and LOW confidence items are flagged throughout and should be validated before engineering implementation begins.

Official Sources by Jurisdiction

Market	Regulator	Key Publication
USA	FDA	eSTAR Program — fda.gov/medical-devices · 21 CFR Part 820 (QMSR)
Canada	Health Canada	REP for Medical Devices — canada.ca/health-canada
EU	European Commission	Regulation (EU) 2024/1860 · EC EUDAMED portal
UK	MHRA	Device registration guidance — mhra.gov.uk
Switzerland	Swissmedic	swissdamed guidance — swissmedic.ch
Australia	TGA	UDI Compliance Timeframes v2.1 — tga.gov.au
China	NMPA	Announcement 2025 No. 132 — nmpa.gov.cn
Egypt	EDA	Regulatory Guideline on UDI for Medical Devices v02/2026 — eda.gov.eg
Indonesia	BPJPH / MoH	Government Regulation No. 42/2024 · MoH Regulation No. 3/2024
Brazil	ANVISA	RDC 591/2021 Art. 15 · SIUD system — anvisa.gov.br
South Africa	SAHPRA	Medical Devices Reliance Guideline · e-IFU requirements
Saudi Arabia	SFDA	MDMA2 guidance · GHAD portal · MDS-G-028 · sfda.gov.sa
South Korea	MFDS	Medical Device GMP Regulations (English) — mfds.go.kr/eng/lbrd/m_40/view.do?seq=72638
India	CDSCO	MDR 2017 · SUGAM portal — cdsco.gov.in
Japan	PMDA/MHLW	UDI-J Implementation Roadmap — pmda.go.jp

RESEARCH DATE

Research conducted: 23 July 2026. This report reflects information available as of that date. Regulatory requirements change frequently — verify all items against official sources before engineering implementation begins.