



SUBMISSION BUILDER UPDATE REPORT

Regulatory Changes Impacting SB Wizards

2025–2026 Global Assessment | MD & IVD New Registration

PERIOD COVERED

2025 – 2026

DATE RULE

Published or Effective in Period

PRODUCT SCOPE

MD + IVD (treated separately)

LIFECYCLE STAGE

New Registration Only

WIZARD INVENTORY — 40 MARKETS

Countries

ARG · AUS · BHR · BOL · BRA · CAN · CHL · CHN · COL · ECU · EGY · EU · HKG · IND · IDN
· ISR · JPN · JOR · KWT · MEX · MAR · NZL · PAK · PER · PRT · SAU · SGP · ZAF · KOR ·
ESP · CHE · TWN · THA · TUR · ARE · GBR · USA · URY · VNM + International

Priority Framework

P0 Blockers → P1 Mandatory → P2 Conditional → P3 Minor → Watchlist

Research Date

July 2026

Confirmed Updates
Found

12 updates across 11 markets (5 P0, 5 P1, 2 P2)

⚠ Engineering Action Required: 5 P0 (release-blocking) changes have confirmed 2026 effective dates. EUDAMED (28 May), Canada REP (1 Apr), USA eSTAR v7 (enforced 2026), UK routing split (28 May), and Switzerland swissdamed (31 Dec deadline) must be prioritized immediately.



Executive Summary

This report identifies and classifies all regulatory changes published or effective during 2025–2026 that require modifications to RegDesk Submission Builder wizards for new product registration (MD and IVD). Research covered all 40 markets in the active wizard inventory.

P0 — 5 Release-Blocking Changes

- USA: eSTAR v7.0 (nIVD + IVD)
- Canada: REP mandatory (Class II–IV MD)
- EU: EUDAMED 4 modules (all MDR/IVDR)
- UK: GB vs. NI routing split
- Switzerland: swissdamed mandatory

P1 — 5 Mandatory Changes

- Australia: UDI Class III + IIb
- China: NMPA Classification Catalogue
- Egypt: UDI Guideline v02/2026
- Indonesia: Halal Class A devices
- Brazil: SIUD/UDI (class-phased)
- South Africa: Reliance + e-IFU

P2 — 2 Conditional / Terminology Updates

USA: QMSR enforcement (21 CFR Part 820 revised — ISO 13485 terminology throughout wizard). South Africa e-IFU conditional branch.

Key Technical Impacts

Impact Type	Markets Affected	Action
Electronic platform migration (new submission system)	USA, Canada, EU, UK, Switzerland	New artifact generation pipeline per platform
Market routing split / branching logic	UK (GB/NI), EU (MDR/IVDR routing)	Explicit branch architecture — cannot share representative fields
UDI data collection	Australia, Egypt, Brazil	UDI applicability rules + post-approval task triggers
Classification catalogue update	China (31 items + RF)	Controlled vocabulary load, class recalculation engine
Religious compliance gate	Indonesia (Class A MD)	Halal branch + exception pathway (Oct 2026)
Reliance pathway	South Africa	Optional reliance branch with equivalence evidence capture
Quality system terminology	USA (all wizards)	Text audit — replace QSR/QSIT with QMSR/ISO 13485 language

Negative Evidence Summary

The following were investigated and excluded from the main register:

- **UAE MOHAP → EDE transfer:** No official instrument with a confirmed date found. Remains Watchlist.
- **Brazil UDI all-class from 1 Mar 2026:** Incorrect — 1 March is SIUD system launch; obligation is class-phased per RDC 591/2021.
- **MHRA post-Brexit reliance pathway:** Still in consultation; not finalized.
- **FDA electronic labeling NPRM:** Proposed rule only — not yet enforceable.



Global Implementation Matrix

All confirmed changes in priority order. P0 = release-blocking; P1 = mandatory with deadline; P2 = confirmed conditional update.

Priority	Market	Authority	Scope	Change	Effective	SB Action
P0	USA	FDA	MD + IVD	eSTAR v7.0 mandatory	2026 (enforced)	Version-lock all 510(k)/PMA/De Novo artifacts to v7.0; separate nIVD vs IVD templates
P0	Canada	Health Canada	MD (Class II–IV)	REP XML mandatory	1 Apr 2026	Replace PDF dossier with REP XML objects (Company, dossier, regulatory transaction); IMDRF ToC
P0	EU	EC / EUDAMED	MD + IVD	EUDAMED 4 modules mandatory	28 May 2026	Wizard must generate Actor/SRN → Basic UDI-DI → UDI-DI/device → packaging records in sequence
P0	UK	MHRA	MD + IVD	GB vs NI routing split	28 May 2026	Explicit GB (MHRA DORS) vs NI (EUDAMED) branch; separate representatives; GMDN for GB DORS
P0	Switzerland	Swissmedic	MD + IVD	swissdamed mandatory	31 Dec 2026	Swiss-specific dataset; CHRN capture; current-law vs legacy branching; not a copy of EUDAMED
P1	Australia	TGA	MD (Class III, IIb)	UDI mandatory scope expansion	2026 (TGA v2.1)	UDI branch for Class III/IIb MD only; AusUDID post-approval 30-day link task
P1	China	NMPA	MD + IVD	Classification Catalogue update (31 items)	4 Jan 2026 (RF: 1 Apr 2026)	Load 31-item table as controlled source; recalculate class/authority/route; RF devices hard Class III
P1	Egypt	EDA	MD + IVD	UDI Guideline v02/2026	2026 (label enforcement TBD)	Structured Egyptian UDI block; Arabic brand/device description for lay-use; GMDN; sterile/reuse/MRI/latex flags
P1	Indonesia	BPJPH / BPOM	MD Class A only	Halal mandatory	18 Oct 2026	Halal branch for Class A MD; collect material origin, halal cert or documented exception; Oct 2026 gate
P1	Brazil	ANVISA	MD + IVD	SIUD/UDI class-phased rollout	System launched 1 Mar 2026; obligation class-phased	Structured UDI dataset; SIUD-to-ANVISA record linkage; phased class applicability per RDC 591/2021
P1	South Africa	SAHPRA	MD	Reliance pathway + e-IFU	2026 (operational)	Optional reliance branch (reference auth + equivalence evidence); conditional e-IFU URL/version fields
P2	USA	FDA	MD + IVD	QMSR — 21 CFR Part 820 revised	Feb 2026 (grace ended)	Text audit: replace all QSR/QSIT references with QMSR/ISO 13485:2016 terminology throughout wizard

Scope note: 29 remaining markets (ARG, AUS Class I/IIa, BHR, BOL, CHL, COL, ECU, HKG, IND, GEN, ISR, JPN, JOR, KWT, MEX, MAR, NZL, PAK, PER, PRT, SAU, SGP, KOR, ESP, TWN, THA, TUR, URY, VNM) — no material confirmed changes to new registration wizard requirements for 2025–2026 were identified. India CDSCO classification list updates were published in 2025 but relate to existing risk classification clarifications, not new registration submission format changes. These markets are included in the Negative Evidence Register.



Detailed Findings — P0 Release-Blocking

P0 USA — eSTAR v7.0 Mandatory Enforcement

FDA | nIVD + IVD | 510(k), De Novo, PMA

CHANGE SUMMARY

FDA is enforcing eSTAR v7.0 across all electronic submission pathways in 2026. The previous version (6.x) produces rejected submissions. Separate artifacts exist for nIVD and IVD pathways. June 2026 Human Factors additions are included.

REQUIRED WIZARD CHANGES

- Maintain separate eSTAR v7.0 source artifacts for nIVD and IVD pathways — do not share a single template
- Version-lock all form field identifiers, JS conditions, and attachment anchors to v7.0 field IDs
- Add Human Factors section fields effective June 2026 (HF test methods, summative study data, HF risk analysis linkage)
- Add submission-state rule: in-progress submissions continue in v6.x; new submissions default to v7.0
- Validate generated output against FDA eSTAR v7.0 acceptance schema before export

ACCEPTANCE TESTS

- Golden-path nIVD 510(k) export → validates against v7.0 schema without errors
- Golden-path IVD 510(k) export → validates against v7.0 IVD schema without errors
- Submission created before cutover date → continues in v6.x without silent conversion
- v6.x field ID in new submission → export fails with version mismatch error

Source: FDA eSTAR Program — fda.gov/medical-devices/eSTAR

P0 Canada — REP (Regulatory Enrolment Process) Mandatory

Health Canada | MD Class II–IV | Effective 1 April 2026

CHANGE SUMMARY

Health Canada mandated REP XML submission format for Class II–IV medical device licence applications effective 1 April 2026. PDF dossier packages are no longer accepted. Class I, MDEL, investigational, and Special Access programs are excluded from the mandate.

REQUIRED WIZARD CHANGES

- Replace PDF output with REP XML objects: Company (CO), dossier, regulatory transaction
- Enforce prerequisite sequence: Company object finalized → dossier → regulatory transaction
- Capture company identity once; reuse across all REP objects with consistent IDs
- Generate IMDRF ToC-compliant dossier structure as secondary QA view
- Produce CESG-ready package (complete electronic submission with cross-references)
- Exclude Class I / MDEL / Investigational / Special Access from REP routing
- Add effective-date gate: REP required for new applications submitted on or after 1 Apr 2026

ACCEPTANCE TESTS

- Class II MD new application → REP XML objects generated, validate against Health Canada schema
- Class I MD new application → no REP XML generated; PDF dossier pathway retained
- Application submitted before 1 Apr 2026 → PDF pathway used; no silent conversion

Source: Health Canada — *Regulatory Enrolment Process (REP) for medical devices* — canada.ca

**P0 EU — EUDAMED First Four Modules Mandatory**

EC / EUDAMED | All MDR + IVDR devices | Effective 28 May 2026

CHANGE SUMMARY

Regulation (EU) 2024/1860 mandates use of the first four EUDAMED modules for all new devices placed on the EU market from 28 May 2026. The wizard must generate valid EUDAMED-compliant records in the prescribed sequence.

REQUIRED WIZARD CHANGES

- Generate records in mandatory sequence: Actor/SRN → Basic UDI-DI → UDI-DI/device registration → Packaging records
- Actor/SRN: capture manufacturer, AR/EC-REP identity using current DTX/XSD enumerations
- Basic UDI-DI: ISO 15223 symbols, clinical size, EMDN code, sterilization method
- Device registration: MDR/IVDR Article 27/26 data elements per current EUDAMED schema
- Packaging: hierarchical levels, DI per level, quantity, UoM
- Enforce cross-object referential integrity (SRN/IDs must match across all modules)
- Schema validation against current EUDAMED DTX/XSD before export

ACCEPTANCE TESTS

- MDR Class IIa device → all 4 module records generated, pass EUDAMED XSD validation
- Missing SRN → export blocked with referential integrity error
- IVDR Class C IVD → separate IVDR pathway with correct Article references

Source: Regulation (EU) 2024/1860; EC EUDAMED portal — ec.europa.eu/health/eudamed

P0 UK — GB vs. NI Routing Split

MHRA | All MD + IVD | Effective 28 May 2026

REQUIRED WIZARD CHANGES

- Replace single UK market output with explicit GB (MHRA DORS) vs. NI (EU MDR/IVDR + EUDAMED) branches
- GB branch: MHRA DORS registration, UKRP identity, GMDN code required, UK-specific classification
- NI branch: EU MDR/IVDR compliance, EUDAMED record, EC-REP for NI — separate from GB UKRP
- Do NOT reuse GB responsible person for NI EC-REP role
- Date-triggered rule: remove legacy combined UK registration path for applications initiated after 28 May 2026

ACCEPTANCE TESTS

- GB only → MHRA DORS output with GMDN; no EUDAMED record
- NI only → EUDAMED-compliant record; no MHRA DORS output
- Both markets → two independent outputs with separate representative identities

Source: MHRA device registration guidance — gov.uk/guidance/register-medical-devices

P0 Switzerland — swissdamed Mandatory Registration

Swissmedic | All MD + IVD | Deadline 31 December 2026

REQUIRED WIZARD CHANGES

- Create Swiss-specific dataset — NOT a copy of EUDAMED; Swiss law requires distinct fields
- Capture CHRN (Swiss registration number) where applicable for legacy devices
- Add current-law vs. legacy-law branching (MedDO compliant vs. prior Swiss law)
- Generate swissdamed-compliant export; validate against Swissmedic-published schema
- Alert on applications without completed swissdamed record after 31 Dec 2026 deadline

Source: Swissmedic swissdamed guidance — swissmedic.ch/swissmedic/en/home/medical-devices/swissdamed.html



Detailed Findings — P1 Mandatory

P1

Australia — UDI Mandatory for Class III and Class IIb MD

TGA | MD Class III + IIb only | 2026 (TGA UDI Compliance Timeframes v2.1)

REQUIRED WIZARD CHANGES

- Add UDI applicability rule: country=AUS AND device_class IN (IIb, III) AND product_type=MD → UDI branch required
- Collect: issuing agency, Primary DI, Unit of Use DI (when base qty > 1), package hierarchy, applicable production identifiers (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 Australian supply; block case closure until linked
- IVD devices explicitly excluded from 2026 UDI scope — do NOT trigger for IVD

Source: TGA — UDI Compliance Timeframes v2.1 (June 2026) — [tga.gov.au](https://www.tga.gov.au)

P1

China — NMPA Classification Catalogue Adjustment (31 items + RF)

NMPA | MD + IVD | Effective 4 Jan 2026 (RF: 1 Apr 2026)

REQUIRED WIZARD CHANGES

- Load official 31-item adjustment table (NMPA Announcement 2025 No. 132) as a version-stamped controlled classification source
- On product name/code match: recalculate device class, responsible authority (NMPA vs. provincial), dossier route, and applicable timelines
- RF therapeutic/skin-treatment devices: hard Class III from 1 April 2026 — add effective-date gate per device category
- Store classification-rule version and effective date on each case for audit trail
- Alert when draft case created before 4 Jan 2026 has a product matching the adjusted table

Source: NMPA Announcement 2025 No. 132 — [nmpa.gov.cn](https://www.nmpa.gov.cn)

P1

Egypt — UDI Guideline v02/2026

EDA | MD + IVD | 2026 (label carrier enforcement date TBD)

REQUIRED WIZARD CHANGES

- Add structured Egyptian UDI block: Primary DI, applicable UDI-PIs (LOT, serial, expiry, mfg date), GMDN code, device class
- Add sterile / reusable / MRI-conditional / latex flags as required fields
- For lay-use devices: collect Arabic brand name and Arabic device description (mandatory for consumer-facing labeling)
- Conditional on label carrier enforcement date — add advisory for applications submitted before enforcement

Source: EDA Regulatory Guideline on Requirements for UDI for Medical Devices v02/2026 — eda.gov.eg

P1

Indonesia — Halal Mandatory for Class A Medical Devices

BPJPH / BPOM | MD Class A only | Effective 18 October 2026

REQUIRED WIZARD CHANGES

- Trigger halal branch ONLY when: country=IDN AND device_class=A AND product_type=MD AND placement_date ≥ 18 Oct 2026
- Halal pathway (Branch A): collect material origin, animal-derived / prohibited-material status, manufacturing-process evidence, halal certificate (number, issuer, validity, scope), label evidence
- Exception pathway (Branch B): collect documented legal basis for exception; required non-halal information and marking
- Block submission if Class A Indonesia and neither halal cert nor documented exception is provided
- Do NOT trigger for Class B, C, D or for IVDs

Source: BPJPH; Indonesia Government Regulation No. 42 of 2024; MOH Regulation No. 3 of 2024



P1 Brazil — SIUD/UDI Class-Phased Rollout ANVISA | MD + IVD | SIUD system launched 1 Mar 2026; obligation class-phased per RDC 591/2021

REQUIRED WIZARD CHANGES

- ⚠ DO NOT implement as "mandatory from 1 March 2026 for all classes" — 1 March is system launch only
- Add class-based applicability check against current RDC 591/2021 Art. 15 phase-in table before triggering UDI branch
- Collect structured UDI dataset: Primary DI, applicable UDI-PIs, device class, package hierarchy
- Generate SIUD-to-ANVISA record linkage: system submits UDI data to SIUD; SIUD links to ANVISA registration number
- Support both manual upload and M2M (machine-to-machine) data submission pathways

Source: ANVISA — SIUD; RDC 591/2021 — anvisa.gov.br

P1 South Africa — Reliance Pathway + Conditional e-IFU SAHPRA | MD | 2026 (SAHPRA reliance guideline operational)

REQUIRED WIZARD CHANGES

- Add optional reliance branch: capture reference authority, foreign authorization number, equivalence declaration / evidence document upload
- Add conditional e-IFU logic: URL/mechanism for electronic IFU, document version, confirmation that printed copy is available on request
- Both branches must be conditional — NOT universal requirements for all applications

Source: SAHPRA Medical Devices Reliance Guideline; SAHPRA e-IFU requirements — sahpra.org.za

P2 — Conditional / Terminology Updates

P2 USA — QMSR Enforcement (21 CFR Part 820 Revised) FDA | MD + IVD | Grace period ended February 2026

REQUIRED WIZARD CHANGES

- Text audit: search and replace all instances of "QSR" / "QSIT" with "QMSR" in all wizard labels, help text, and export labels
- Update applicability prompts to reference ISO 13485:2016 + FDA-specific requirements (not ISO 13485 cert alone)
- Do NOT add new mandatory QMS certification fields — QMSR does not require ISO 13485 certification for every registration
- Version-stamp updated wizard sections with guidance reference

Source: 21 CFR Part 820 (revised) — FDA QMSR Final Rule — fda.gov

Watchlist

Market	Change	Status	Why Not Included	Next Milestone
UAE	MOHAP → EDE full transfer	Unverified	No official instrument with confirmed date found	Monitor EDE portal for official transfer announcement
UK	MHRA post-Brexit reliance pathway	Consultation	Still in proposal stage — not finalized	Monitor MHRA consultations
USA	FDA electronic labeling NPRM	Proposed rule	NPRM only — not yet final rule	Monitor Federal Register for Final Rule publication
EU	AI Act applicability to devices	Unresolved	Applicability for 2026 not finalized for device wizards	Monitor EC implementing acts
Japan	PMDA e-submission expansion	Unverified scope	Scope of expansion for new device registrations not confirmed	Monitor PMDA eCTD guidance updates



Recommended Release Sequence

Immediate (Q3 2026 — already past deadline): Canada REP (1 Apr), EU EUDAMED (28 May), UK GB/NI split (28 May), USA eSTAR v7.0 (enforced). These are already in the enforcement window — any delays have direct client impact.

Wave	Changes	Deadline	Priority
Wave 1 (Immediate)	USA eSTAR v7.0 · Canada REP · EU EUDAMED · UK GB/NI split	Already effective	P0
Wave 2 (Q4 2026)	Switzerland swissdamed · China NMPA catalogue · Indonesia Halal (Oct)	By 31 Oct / 31 Dec 2026	P0 P1
Wave 3 (Q4 2026)	Australia UDI · Egypt UDI · Brazil SIUD · South Africa reliance	By end 2026	P1
Wave 4 (Ongoing)	USA QMSR terminology · Watchlist monitoring	Rolling	P2 WL

Validation & QA Plan

Change	Test Type	Test Scenario	Pass Condition
USA eSTAR v7.0	Schema validation	Export nIVD 510(k) in new wizard	Output validates against FDA v7.0 XSD without errors
USA eSTAR v7.0	Regression	Open pre-cutover case	Case remains in v6.x; no silent upgrade
Canada REP	Schema validation	Export Class III MD REP package	All XML objects (CO, dossier, transaction) validate against Health Canada schema
Canada REP	Boundary	Class I MD new application	REP XML not generated; PDF pathway available
EU EUDAMED	Sequence validation	Create MDR Class IIb device record	All 4 module records generated in correct sequence; XSD validation passes
EU EUDAMED	Referential integrity	Submit with missing SRN	Export blocked; integrity error displayed
UK GB/NI	Routing	GB-only selection	MHRA DORS output only; no EUDAMED record
UK GB/NI	Routing	Both markets selected	Two independent outputs; separate representative identities
Switzerland swissdamed	Data validation	Swiss device new registration	swissdamed export generated; Swiss fields distinct from EUDAMED fields
Australia UDI	Applicability	Class IIb MD for Australia	UDI branch shown; post-approval 30-day task created on registration
Australia UDI	Applicability	IVD for Australia	UDI branch NOT shown
China NMPA	Classification	Product matching adjusted table entry	New class and authority displayed; old class not selectable
Indonesia Halal	Branch	Class A MD Indonesia post-Oct 2026	Halal branch displayed; submission blocked without cert or exception
Indonesia Halal	Boundary	Class B MD Indonesia	Halal branch NOT displayed
Brazil SIUD	Phase-in	Class for which RDC 591/2021 deadline not yet reached	UDI branch NOT triggered; advisory note shown
USA QMSR	Text audit	Search wizard UI for "QSR" or "QSIT"	Zero occurrences found



Screened but Excluded Items — Negative Evidence Register

The following claims were investigated and excluded from the main register. They may NOT be re-promoted without a new verified official source and confirmed effective date.

Market	Claim Investigated	Reason Excluded
UAE	MOHAP → EDE full transfer beginning Jan 2026 with P0 impact	No official instrument with a confirmed date found. Date and scope are unverified. Remains Watchlist.
Brazil	UDI mandatory for all classes from 1 March 2026	Misreads SIUD launch date as universal obligation date. RDC 591/2021 Art. 15 specifies class-based phase-in. Corrected to P1 conditional in main register.
UK	MHRA post-Brexit reliance pathway finalized 2026	Still in consultation/proposal stage. No final regulatory instrument published as of research date.
USA	FDA electronic labeling NPRM as 2026 requirement	NPRM (proposed rule) only — not yet promulgated as final rule. Not enforceable.
India	New CDSCO e-submission system for MD registration 2025–2026	CDSCO published updated risk classification lists and guidance documents in 2025. No new mandatory electronic submission system or registration format change confirmed for new registrations within scope.
Japan	PMDA eCTD/e-submission expansion for new device registrations 2025–2026	PMDA has ongoing digital initiatives but no confirmed mandatory scope expansion for new device new registration submissions within 2025–2026 period found.
Singapore	HSA new medical device submission portal 2025–2026	HSA PRISM portal is established system. No confirmed mandatory platform migration or new submission format change identified for 2025–2026.
South Korea	MFDS new foreign device registration requirements 2025–2026	No confirmed material changes to new device registration wizard requirements found for 2025–2026 within research scope.
EU AI Act	AI Act applicability to devices creating new wizard fields in 2026	AI Act implementing acts for devices not finalized for 2026. Not actionable for wizard development.
ARG, BHR, BOL, CHL, COL, ECU, HKG, ISR, JOR, KWT, MEX, MAR, NZL, PAK, PER, SGP, ESP, PRT, TWN, THA, TUR, URY, VNM	Any material confirmed change to new registration wizard for MD or IVD in 2025–2026	No confirmed official publications with material wizard impact identified within research scope and period. Markets continue under existing wizard configuration.

Sources by Jurisdiction

Market	Authority	Source	URL
USA	FDA	eSTAR Program	fda.gov/medical-devices/eSTAR
USA	FDA	21 CFR Part 820 QMSR Final Rule	fda.gov
Canada	Health Canada	REP for medical devices	canada.ca/health-canada
EU	EC	Regulation (EU) 2024/1860; EUDAMED portal	ec.europa.eu/health/eudamed
UK	MHRA	Register medical devices guidance	gov.uk/guidance/register-medical-devices
Switzerland	Swissmedic	swissdamed guidance	swissmedic.ch
Australia	TGA	UDI Compliance Timeframes v2.1 (June 2026)	tga.gov.au
China	NMPA	Announcement 2025 No. 132	nmpa.gov.cn
Egypt	EDA	UDI Guideline v02/2026	eda.gov.eg
Indonesia	BPJPH / MOH	Gov. Regulation No. 42/2024; MOH Regulation No. 3/2024	jdih.kemkes.go.id
Brazil	ANVISA	RDC 591/2021; SIUD portal	anvisa.gov.br
South Africa	SABRA	Medical Devices Reliance Guidelines: e-IFU requirements	sabra.org.za