

2026 Regulatory Update Report

Submission Builder Wizard Impact Assessment

Version 1.0 | July 2026

Scope: Medical Devices (MD) & IVDs | New Registrations

Classification: Confidential — Internal Use Only

This report provides an engineering-grade impact assessment of 2026 regulatory authority changes that require updates to RegDesk Submission Builder wizard logic, field definitions, and export packages. It covers 12 confirmed changes across 11 jurisdictions, prioritized P0–P2, with a Watchlist of 5 emerging items.

5	6	1	5	11
P0 Critical Blockers	P1 High Priority	P2 Medium Priority	Watchlist Items	Jurisdictions Affected

1. Executive Summary

Five P0 critical blockers require immediate engineering action before Q3 2026. These changes affect core wizard routing, submission package generation, and regulatory compliance for key markets (USA, Canada, EU, UK, Switzerland). Additionally, six P1 high-priority changes are mandatory with confirmed 2026 deadlines across Australia, China, Egypt, Indonesia, Brazil, and South Africa. One P2 item (USA QMSR) requires terminology and content updates. A Watchlist of five items must be monitored for activation.

P0 Critical Blockers — Immediate Action Required

■ ■ USA — eSTAR v7.0	Authority: FDA Deadline: 2026
Change: Separate XFA artifacts per pathway, version-locked field IDs, June 2026 HF module additions. Scope: 510(k), De Novo, PMA, PDP.	
Wizard Impact: New eSTAR v7.0 XFA parser per pathway; field ID migration; HF module integration.	
■ ■ Canada — REP Mandatory	Authority: Health Canada Deadline: 1 Apr 2026
Change: Regulatory Enrolment Process mandatory from 1 Apr 2026 for Class II–IV. REP XML objects, IMDRF TOC structure, CESSG-ready package.	
Wizard Impact: New REP XML builder module; wizard branch for Class II–IV; CESSG package export.	
■ ■ EU — EUDAMED Mandatory	Authority: European Commission Deadline: 28 May 2026
Change: 28 May 2026: First 4 EUDAMED modules mandatory for all new MDR/IVDR devices. Actor registration → Basic UDI-DI → UDI-DI/device data → packaging.	
Wizard Impact: EUDAMED 4-module sequential flow; DTX/XSD schema integration; mandatory for all EU submissions.	
■ ■ UK — GB vs. NI Routing Split	Authority: MHRA Deadline: 28 May 2026
Change: Explicit GB (MHRA DORS) vs. NI (EU MDR/IVDR + EUDAMED) wizard branch from 28 May 2026. GMDN code mandatory for GB DORS.	
Wizard Impact: Routing branch logic; GMDN field for GB; remove duplicate NI MHRA registration.	
■ ■ Switzerland — swissdamed Mandatory	Authority: Swissmedic Deadline: 31 Dec 2026
Change: swissdamed registration mandatory by 31 Dec 2026. Swiss-specific dataset, CHRN number field, current-law vs. legacy branching.	
Wizard Impact: New swissdamed module; CHRN field; branching for current vs. legacy law applicants.	

Recommended Release Sequence (Overview)

Phase	Priority	Timing	Jurisdictions
Phase 1 — Critical	P0	Immediate / Q3 2026	USA (eSTAR), Canada (REP), EU (EUDAMED), UK (GB/NI), Switzerland
Phase 2 — High Priority	P1	Q2–Q3 2026	Australia, China, Egypt, Indonesia, Brazil, South Africa
Phase 3 — Content Updates	P2	Q3–Q4 2026	USA (QMSR terminology)

Phase	Priority	Timing	Jurisdictions
Phase 4 — Monitoring	Watchlist	Ongoing	UAE, EU AI Act, Japan, UK post-Brexit, FDA e-labeling

2. Scope and Methodology

Report Scope

This report covers 2026 regulatory authority changes that directly impact the RegDesk Submission Builder (SB) wizard — including field additions, route branching, schema updates, controlled vocabulary changes, and new mandatory submission modules. Coverage: Both MD (Medical Devices) and IVD (In Vitro Diagnostics). Application type: New registrations (not renewals or amendments unless noted).

Priority Framework

P0 — Critical Blockers: Change is live/imminent; non-compliance blocks legal market access. Immediate engineering action required.

P1 — High Priority: Mandatory with confirmed deadline in 2026; significant wizard changes required.

P2 — Medium Priority: Mandatory but lower structural impact; terminology/content updates sufficient.

Watchlist: Emerging or unconfirmed; no official instrument confirmed; monitor only.

Data Sources

All findings are based on official regulatory authority publications, gazette notices, regulatory guidance documents, and authority portals as of July 2026. Watchlist items have been deliberately excluded from actionable categories pending confirmation of official instruments.

Out of Scope

Renewal submissions, post-market change applications, and country-specific device classification guidance outside the scope of SB wizard logic. Watchlist items are monitored but not actioned until confirmed.

3. Global Implementation Matrix

The following matrix provides a consolidated view of all 12 confirmed regulatory changes affecting Submission Builder wizards in 2026, ordered by priority and effective date.

Priority	Jurisdiction	Authority	Product Scope	Change Summary	Effective Date	SB Impact	Action
P0	USA	FDA	MD + IVD 510(k)/De Novo/ PMA/PDP	eSTAR v7.0: new XFA artifacts per pathway, version-locked field IDs, HF module	2026 (HF: Jun 2026)	High — new parser, field migration, module addition	Immediate
P0	Canada	Health Canada	MD: Class II–IV	REP mandatory: XML objects, IMDRF TOC structure, CESC-ready package	1 Apr 2026	High — new REP builder, wizard branch, package export	Immediate
P0	EU	EC / EUDAMED	MD + IVD (MDR/IVDR)	EUDAMED modules 1–4 mandatory for all new submissions	28 May 2026	Critical — sequential 4-module flow, DTX/XSD schema	Immediate
P0	UK	MHRA	MD + IVD	GB (DORS) vs. NI (EUDAMED) routing split; GMDN mandatory for GB	28 May 2026	High — routing branch, GMDN field, NI deduplication	Immediate
P0	Switzerland	Swissmedic	MD + IVD	swissdamed mandatory; Swiss dataset, CHRN number, law-version branching	31 Dec 2026	High — new module, CHRN field, branching logic	Immediate
P1	Australia	TGA	MD: Class III + IIb (not IVD in 2026)	UDI mandatory for Class III/IIb: Primary DI, issuing agency, AusUDID linkage	Jun 2026	Medium — conditional UDI block, AusUDID task	Q2 2026
P1	China	NMPA	MD + IVD	Classification catalogue update: 31-item reclassification, RF devices → Class III	4 Jan / 1 Apr 2026	Medium — vocabulary update, class recalculation	Q1 2026
P1	Egypt	EDA	MD + IVD	UDI Guideline v02/2026: structured UDI block, Arabic fields for lay-use	2026	Medium — UDI block, Arabic fields, flag fields	Q2 2026
P1	Indonesia	BPJPH	MD: Class A only	Halal mandatory for Class A: material origin, animal components, certificate upload	18 Oct 2026	Medium — new Halal section, conditional on Class A	Q3 2026
P1	Brazil	ANVISA	MD + IVD (class-phased)	SIUD/UDI operational Mar 2026; class-phased obligation per RDC 591/2021 Art.15	1 Mar 2026 (phased)	Medium — UDI dataset, SIUD linkage, class gating	Q2 2026
P1	South Africa	SAHPRA	MD + IVD (conditional)	Reliance branch (optional) + conditional e-IFU logic	2026	Low-Medium — conditional branches, NOT universal	Q2–Q3 2026
P2	USA	FDA	MD + IVD	QMSR enforcement: replace QSR/QSIT with QMSR terminology; reference ISO 13485:2016	Feb 2026 (grace ended)	Low — terminology/content update only	Q3 2026

■ P0 — Critical Blocker

■ P1 — High Priority

■ P2 — Medium Priority

■ Watchlist — Monitor Only

4. Detailed Findings by Jurisdiction

4.1 — ■■ USA — eSTAR v7.0

P0

Authority: FDA (Center for Devices and Radiological Health — CDRH)

Effective: 2026 (HF module additions: June 2026)

Change Summary

FDA has released eSTAR v7.0, requiring separate XFA artifacts per pathway (nIVD and IVD versions). Version-locked field IDs break backward compatibility with eSTAR v6.x parsers. A new Human Factors (HF) module was added in June 2026, applicable to 510(k), De Novo, PMA, and PDP submissions.

Products Affected

510(k) Traditional, De Novo, PMA, PDP — both MD and IVD

Previous State	New Requirement
eSTAR v6.x single XFA template; HF data captured in free-text narrative fields	eSTAR v7.0: separate XFA per pathway; version-locked field IDs; structured HF module with discrete fields

Wizard Changes Required (Field-Level)

- Deploy separate v7.0 XFA parsers for nIVD and IVD pathways
- Migrate all field ID references from v6.x schema to v7.0 locked IDs
- Add Human Factors wizard section: usability study type, formative/summative status, HF report reference, user population fields
- Implement pathway-conditional XFA artifact selection at submission init
- Version detection logic: reject v6.x XFA on v7.0-required submissions

Recommended QA Tests

1. Submit test 510(k) via v7.0 nIVD XFA — verify all required fields export correctly
2. Submit test IVD 510(k) via v7.0 IVD XFA — verify pathway-specific fields
3. Attempt v6.x field ID submission — verify rejection/warning triggered
4. Complete HF module for usability-tested device — verify all HF fields captured
5. Verify eSTAR package accepted by FDA ESG test gateway

Source: FDA eSTAR Program — <https://www.fda.gov/medical-devices/how-study-and-market-your-device/electronic-submissions-gateway>

4.2 — ■■ Canada — REP Mandatory

P0

Authority: Health Canada (Medical Devices Directorate)

Effective: 1 April 2026

Change Summary

The Regulatory Enrolment Process (REP) became mandatory for all Class II–IV medical device applications from 1 April 2026. REP requires submission of structured XML objects covering Company CO, dossier, and regulatory transaction data, organized under the IMDRF Table of Contents structure. The final package must be CESG (Canada's Electronic Submission Gateway) ready.

Products Affected

Class II, III, and IV medical devices (MD). IVD Class II–IV also affected.

Previous State	New Requirement
Manual application submission; no structured XML enrollment package required	REP XML package mandatory: Company CO, dossier XML, regulatory transaction XML; IMDRF TOC structure; CESG delivery

Wizard Changes Required (Field-Level)

- New REP wizard branch triggered for all Canada Class II–IV submissions
- REP Company CO XML builder: legal entity name, establishment details, contact

- Dossier XML object builder: IMDRF TOC structure, module references
- Regulatory transaction XML: submission type, reference numbers, payment fields
- CESC package assembly: bundle all XML objects + attachments in CESC format
- Class I submissions: REP not applicable — ensure Class I bypass route works

Recommended QA Tests

1. Canada Class II submission — verify REP branch triggered automatically
2. Verify Company CO XML validates against Health Canada REP schema
3. Verify IMDRF TOC structure matches current Health Canada guidance
4. Attempt Canada Class I submission — verify REP branch is NOT triggered
5. Test CESC package download — validate format accepted by CESC test portal

Source: Health Canada REP — <https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/applications-submissions/regulatory-enrolment-process.html>

4.3 — ■■ EU — EUDAMED Mandatory

P0

Authority: European Commission / EUDAMED Portal

Effective: 28 May 2026

Change Summary

Regulation (EU) 2024/1860 made the first four EUDAMED modules mandatory from 28 May 2026 for all new MDR and IVDR device registrations. The four modules must be completed sequentially: (1) Actor Registration, (2) Basic UDI-DI registration, (3) UDI-DI/Device Data, (4) Packaging. Current DTX/XSD schema enumerations and controlled vocabularies must be used.

Products Affected

All MDR/IVDR devices — MD and IVD — new registrations

Previous State	New Requirement
EUDAMED optional/voluntary; EU MDR/IVDR submission without mandatory EUDAMED pre-registration	Sequential 4-module EUDAMED flow mandatory for all new MDR/IVDR submissions; DTX/XSD schema compliance required

Wizard Changes Required (Field-Level)

- New mandatory EUDAMED wizard block for all EU submissions (MDR/IVDR)
- Module 1: Actor Registration — SRN (Single Registration Number) capture/lookup
- Module 2: Basic UDI-DI — issuing agency, UDI-DI value, basic device type
- Module 3: UDI-DI/Device Data — full device description per EUDAMED schema
- Module 4: Packaging — packaging hierarchy levels, UDI-PIs per level
- DTX/XSD schema validation for all EUDAMED data fields
- Sequential enforcement: Module N cannot complete without Module N-1 SRN/reference

Recommended QA Tests

1. EU MDR submission — verify EUDAMED 4-module block is triggered and required
2. Test Module 1 SRN lookup — verify existing SRN retrieval and new SRN registration flow
3. Validate Module 2 Basic UDI-DI against current DTX/XSD enumeration
4. Test Module 4 packaging hierarchy with 3 levels — verify UDI-PI fields per level
5. Attempt Module 3 without completing Module 2 — verify blocking validation
6. IVD IVDR submission — verify same EUDAMED block applies

Source: Regulation (EU) 2024/1860; EUDAMED portal — <https://ec.europa.eu/tools/eudamed>

4.4 — ■■ UK — GB vs. NI Routing Split

P0

Authority: MHRA (Medicines and Healthcare products Regulatory Agency)

Effective: 28 May 2026

Change Summary

From 28 May 2026, the UK wizard must implement explicit routing for Great Britain (GB) and Northern Ireland (NI) as separate pathways. GB devices register via MHRA DORS with GMDN code mandatory. NI devices follow EU MDR/IVDR pathway with full EUDAMED registration. Duplicate MHRA registration for non-custom NI devices must be removed post-May 2026.

Products Affected

All MD and IVD for UK market (GB and/or NI)

Previous State	New Requirement
UK treated as single market; MHRA registration for all UK; GMDN optional	GB (DORS + GMDN mandatory) vs. NI (EU MDR/IVDR + EUDAMED) separate wizard branches; NI MHRA duplicate removed

Wizard Changes Required (Field-Level)

- UK market routing question: intended market = GB only / NI only / both GB and NI
- GB branch: MHRA DORS registration flow, GMDN code as mandatory field
- NI branch: Route to EU MDR/IVDR + EUDAMED module (as per 4.3)
- Both: Combined GB + NI submission — both branches required sequentially
- Remove MHRA registration requirement for non-custom NI devices post-28 May 2026
- GMDN lookup/validation: integrate GMDN database lookup or manual entry with format validation

Recommended QA Tests

1. UK submission, GB market only — verify DORS branch + GMDN mandatory
2. UK submission, NI market only — verify EU MDR/IVDR + EUDAMED branch
3. UK submission, GB + NI — verify both branches triggered sequentially
4. Attempt DORS submission without GMDN — verify blocking validation
5. NI non-custom device post-May 2026 — verify NO MHRA registration required

Source: MHRA — <https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market>

4.5 — Switzerland — swissdamed Mandatory

P0

Authority: Swissmedic

Effective: 31 December 2026

Change Summary

All medical devices placed on the Swiss market must be registered in swissdamed by 31 December 2026. The swissdamed dataset is Swiss-specific — it is NOT a copy of EUDAMED data. A CHRN (Complementary and Herbal Registration Number) field applies where relevant. The wizard must distinguish between devices registered under current Swiss law vs. devices with legacy Swissmedic approvals.

Products Affected

All MD and IVD placed on Swiss market

Previous State	New Requirement
Switzerland used EUDAMED data or manual Swissmedic submission; no swissdamed module in wizard	New swissdamed module mandatory by Dec 2026; Swiss-specific dataset; CHRN field; current vs. legacy law branching

Wizard Changes Required (Field-Level)

- New swissdamed wizard module for Switzerland submissions
- Swiss-specific fields: device description (Swiss requirements), swissdamed ID lookup
- CHRN number field: conditional on device type/classification
- Law-version branching: current Swiss MedDO law vs. legacy Swissmedic approval pathway
- Explicit warning/note: swissdamed data is NOT auto-populated from EUDAMED
- Submission package: swissdamed export separate from EU EUDAMED package

Recommended QA Tests

1. Switzerland submission — verify swissdamed module is triggered
2. Verify Swiss-specific fields are NOT auto-copied from EUDAMED data
3. Test CHRN field: conditional trigger for applicable device types

4. Test current-law branch vs. legacy-law branch — verify different field sets
5. Verify swissdamed export package is distinct from EU EUDAMED export

Source: *Swissmedic swissdamed* — <https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/swissdamed.html>

4.6 — ■■ Australia — UDI Class III & IIb

P1

Authority: TGA (Therapeutic Goods Administration)

Effective: June 2026 (per TGA UDI compliance timeframes v2.1)

Change Summary

TGA UDI compliance timeframes v2.1 (June 2026) require UDI for Class III and Class IIb medical devices. IVDs are excluded from this 2026 requirement. Post-approval, a 30-day AusUDID link task is required. The wizard must capture: issuing agency, Primary DI, and packaging hierarchy.

Products Affected

MD Class III and IIb only. IVDs excluded from 2026 UDI requirement.

Previous State	New Requirement
No UDI requirement in Australian wizard; AusUDID link not captured	UDI conditional on Class III/IIb (MD only); Primary DI, issuing agency, package hierarchy; AusUDID 30-day post-approval task

Wizard Changes Required (Field-Level)

- UDI applicability gate: Class III or IIb = UDI section required; all others = skip
- IVD gate: IVD submissions skip UDI section in 2026
- UDI fields: issuing agency (GS1/HIBCC/ICCBBA), Primary DI value, Secondary DI (if applicable)
- Packaging hierarchy: up to 3 levels, UDI-PI per level
- Post-approval task: AusUDID 30-day link instruction in submission checklist
- AusUDID record ID field: optional at submission, required post-approval

Recommended QA Tests

1. Australia Class III submission — verify UDI section triggered
2. Australia Class IIb submission — verify UDI section triggered
3. Australia Class I submission — verify UDI section NOT triggered
4. Australia IVD submission (any class) — verify UDI section NOT triggered in 2026
5. Verify AusUDID 30-day post-approval task appears in checklist

Source: *TGA UDI* — <https://www.tga.gov.au/industry/medical-devices/unique-device-identification-udi>

4.7 — ■■ China — NMPA Classification Catalogue

P1

Authority: NMPA (National Medical Products Administration)

Effective: 4 January 2026 (general); 1 April 2026 (RF therapeutic/skin devices → Class III)

Change Summary

NMPA Announcement 2025 No. 132 (effective 4 January 2026) updated the medical device classification catalogue with 31 reclassified items. RF therapeutic and skin-treatment devices are reclassified to Class III effective 1 April 2026. The wizard must load the 31-item reclassification as controlled vocabulary and recalculate device class, regulatory authority, and dossier route.

Products Affected

MD and IVD subject to 31-item reclassification; RF therapeutic/skin-treatment devices specifically

Previous State	New Requirement
Pre-2026 NMPA classification catalogue; RF therapeutic/skin devices classified as Class II	Updated catalogue with 31 reclassifications effective 4 Jan 2026; RF therapeutic → Class III from 1 Apr 2026

Wizard Changes Required (Field-Level)

- Load updated NMPA classification catalogue as controlled vocabulary (31 changes)

- Device type picker: trigger reclassification warning for affected categories
- Class recalculation: if device type matches reclassification list → auto-update class
- Dossier route recalculation: Class III NMPA → NMPA National review (not provincial)
- Date-gated logic: RF therapeutic/skin devices → Class III only after 1 Apr 2026
- Warning banner: devices reclassified since initial wizard session started

Recommended QA Tests

1. Select RF therapeutic device type — verify Class III triggered from 1 Apr 2026
2. Select RF skin-treatment device — verify Class III triggered from 1 Apr 2026
3. Verify dossier route changes to NMPA National for newly Class III devices
4. Date-gate test: RF device submission before 1 Apr 2026 — verify Class II still applies
5. Verify all 31 reclassification items load correctly in classification picker

Source: NMPA Announcement 2025 No. 132

4.8 — ■■ Egypt — UDI Guideline v02/2026

P1

Authority: EDA (Egyptian Drug Authority — Medical Devices Sector) **Effective:** 2026 (EDA Regulatory Guideline v02/2026)

Change Summary

EDA Regulatory Guideline on UDI for Medical Devices v02/2026 requires a structured Egyptian UDI block in all new device registrations. The block includes: Primary DI, UDI-PIs, GMDN code, device class, and flag fields for sterility, reusability, MRI safety, and latex content. Arabic-language brand name and device description are additionally required for lay-use devices.

Products Affected

All MD and IVD — new Egypt registrations

Previous State	New Requirement
No structured UDI requirement in Egypt wizard; Arabic fields not required	Structured Egyptian UDI block; Primary DI + UDI-PIs; GMDN; flag fields; Arabic brand name and description for lay-use

Wizard Changes Required (Field-Level)

- New Egyptian UDI section in Egypt wizard
- Primary DI field: issuing agency + DI value
- UDI-PI fields: lot/batch, serial, manufacturing date, expiry date (conditional on device type)
- GMDN code: mandatory Egyptian requirement
- Device class field: maps to Egypt EDA classification
- Flag fields (boolean): Is sterile? Is reusable? MRI safety status? Contains latex?
- Lay-use conditional: if device is for lay use → Arabic brand name + Arabic device description required

Recommended QA Tests

1. Egypt submission — verify UDI block section is triggered
2. Verify Primary DI + issuing agency fields present and validated
3. Verify GMDN code field is mandatory for Egypt
4. Lay-use device — verify Arabic brand name + Arabic description required
5. Non-lay-use device — verify Arabic fields are optional/hidden
6. Verify all 4 flag fields (sterility/reuse/MRI/latex) are captured

Source: EDA Regulatory Guideline on UDI for Medical Devices v02/2026

4.9 — ■■ Indonesia — Halal Mandatory (Class A)

P1

Authority: BPJPH (Halal Product Assurance Organizing Body) + Ministry of Health **Effective:** 18 October 2026

Change Summary

Government Regulation No. 42/2024 and Ministry of Health Regulation No. 3/2024 make Halal certification mandatory for Class A medical devices from 18 October 2026. The wizard must capture: material origin, animal-derived component status, manufacturing process evidence, and either a Halal certificate upload or a documented exception pathway.

Products Affected

MD Class A only. IVD and Class B/C/D: not subject to this 2026 requirement.

Previous State	New Requirement
No Halal section in Indonesia wizard; Class A devices had no Halal requirement	Halal mandatory for Class A MD from 18 Oct 2026; material origin, animal components, certificate upload OR exception pathway

Wizard Changes Required (Field-Level)

- Indonesia Class A gate: trigger Halal section for Class A MD submissions
- Material origin field: primary materials list with origin (plant/animal/synthetic/mineral)
- Animal-derived components: binary field + component detail if yes
- Manufacturing process evidence: upload field for halal manufacturing documentation
- Halal certification pathway: upload Halal certificate (BPJPH-issued or recognized body)
- Exception pathway: if no Halal certificate → documented exception justification upload
- Conditional logic: certificate pathway vs. exception pathway — mutually exclusive

Recommended QA Tests

1. Indonesia Class A MD — verify Halal section triggered from 18 Oct 2026
2. Indonesia Class B MD — verify Halal section NOT triggered
3. Test certificate pathway: upload valid Halal certificate — verify acceptance
4. Test exception pathway: verify exception justification upload is accepted
5. Verify exception and certificate pathways are mutually exclusive (cannot select both)
6. Test date-gate: submission before 18 Oct 2026 — verify Halal not yet required

Source: Government Regulation No. 42/2024; Ministry of Health Regulation No. 3/2024

4.10 — ■■ Brazil — SIUD/UDI (Class-Phased)

P1

Authority: ANVISA

Effective: 1 March 2026 (SIUD operational); class-phased obligation per RDC 591/2021

Change Summary

The Brazilian SIUD (Sistema de Identificação Única de Dispositivos) system became operational 1 March 2026. IMPORTANT: UDI is NOT universally mandatory from 1 March 2026 — obligation follows a class-based timeline per RDC 591/2021 Art. 15. The wizard must add a structured UDI dataset and SIUD-to-ANVISA record linkage, with class-based gating for when UDI becomes mandatory.

Products Affected

MD and IVD — class-phased per RDC 591/2021 Art. 15 timeline

Previous State	New Requirement
No UDI requirement in Brazil wizard; SIUD system not operational	SIUD operational; class-phased UDI obligation (not universal from Mar 2026); structured UDI dataset + SIUD linkage required

Wizard Changes Required (Field-Level)

- UDI applicability check: query device class against RDC 591/2021 Art. 15 phase table
- If UDI applicable: Primary DI (issuing agency + DI value), UDI-PIs (lot, serial, dates)
- Package hierarchy: up to 3 levels, UDI per level
- SIUD linkage field: SIUD registration ID (post-ANVISA approval)
- Clear warning: UDI obligation is CLASS-PHASED — do not apply universally to all Class I
- ANVISA-SIUD record link: post-submission task in checklist

Recommended QA Tests

1. Brazil Class III submission — verify UDI triggered per Art. 15 phase
2. Brazil Class I submission — verify UDI trigger follows correct phase date
3. Verify SIUD linkage field appears post-approval in submission checklist
4. Verify universal UDI trigger is NOT applied to all classes from 1 Mar 2026
5. Verify package hierarchy fields for 2-level packaging

Source: ANVISA RDC 591/2021; SIUD portal

4.11 — ■■ South Africa — SAHPRA Reliance + e-IFU

P1

Authority: SAHPRA (South African Health Products Regulatory Authority)
Effective: 2026

Change Summary

SAHPRA's 2026 Medical Devices Reliance Guideline introduces an optional reliance pathway and conditional e-IFU (electronic Instructions for Use) logic. Reliance is NOT mandatory — it is an optional branch where applicants can reference a foreign authorization. e-IFU is conditional, not universal. Both are wizard branches, NOT default requirements.

Products Affected

All MD and IVD — South Africa new registrations (conditional application)

Previous State	New Requirement
No SAHPRA reliance branch; e-IFU not addressed in wizard	Optional reliance branch (reference authority, foreign authorization, equivalence evidence); conditional e-IFU logic

Wizard Changes Required (Field-Level)

- Reliance branch: optional wizard question 'Do you wish to use a reliance pathway?'
- If reliance: reference authority field, foreign authorization number, date of authorization, equivalence declaration upload
- e-IFU conditional logic: 'Will device use e-IFU instead of printed IFU?'
- If e-IFU: URL/access mechanism field, document version, printed copy availability statement
- Both branches are fully optional — non-selection is valid
- Ensure SAHPRA standard pathway is NOT blocked if neither branch is selected

Recommended QA Tests

1. SA submission with reliance selected — verify all reliance fields appear
2. SA submission with reliance NOT selected — verify no reliance fields shown
3. SA submission with e-IFU selected — verify URL, version, printed statement fields
4. SA submission with e-IFU NOT selected — verify e-IFU fields hidden
5. Verify standard SAHPRA pathway completes successfully with no optional branches selected

Source: SAHPRA Medical Devices Reliance Guideline

4.12 — ■■ USA — QMSR Enforcement

P2

Authority: FDA (CDRH)
Effective: February 2026 (grace period ended)

Change Summary

FDA's Quality Management System Regulation (QMSR) grace period ended February 2026. QSR and QSIT terminology must be replaced with QMSR throughout the wizard. References should cite ISO 13485:2016 plus the FDA-specific addendum. IMPORTANT: QMSR compliance is the standard — do NOT require ISO 13485 certification for every registration (certification is not universally required).

Products Affected

All FDA MD and IVD submissions with quality system declarations

Previous State	New Requirement
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QSR/QSIT terminology; references to 21 CFR Part 820 (QSR) only

QMSR terminology; ISO 13485:2016 + FDA addendum references;
QMSR compliance (not ISO certification) as standard

Wizard Changes Required (Field-Level)

- Replace all QSR/QSIT labels and help text with QMSR
- Update regulatory reference from '21 CFR Part 820 (QSR)' to '21 CFR Part 820 (QMSR)'
- Add ISO 13485:2016 + FDA-specific addendum as cited standard
- Quality system declaration: 'Compliant with QMSR (21 CFR Part 820)' — not 'ISO 13485 certified'
- If ISO 13485 certification is captured: make it optional/conditional, not required

Recommended QA Tests

1. Verify no 'QSR' or 'QSIT' labels remain in US wizard pages
2. Verify quality system declaration uses QMSR terminology
3. Verify ISO 13485 certification field is optional (not blocking)
4. Verify QMSR reference cites correct 21 CFR Part 820 designation
5. Check all help text and tooltips for QSR → QMSR updates

Source: FDA QMSR — 21 CFR Part 820; Federal Register (Feb 2024 final rule, Feb 2026 grace period end)

5. Technical Change Matrix

Field-level engineering specification for each required wizard change, including current state, required state, export impact, and deadline.

Jurisdiction	Wizard Module	Current State	Required State	Field/Logic Change	Export Impact	Deadline
USA (eSTAR)	eSTAR XFA Parser	v6.x unified XFA	v7.0 separate XFA per pathway	Pathway-conditional XFA artifact selection; version-locked field IDs	New eSTAR v7.0 XML package	2026
USA (eSTAR)	Human Factors Module	Free-text HF narrative	Structured HF module: study type, formative/summative, user population	New HF section with discrete fields	HF data captured in eSTAR v7.0 package	Jun 2026
Canada	REP Builder	No REP module	REP XML package: Company CO, dossier, regulatory transaction	New REP wizard branch; IMDRF TOC; CESG assembly	REP XML + CESG delivery package	1 Apr 2026
EU	EUDAMED Flow	Optional/voluntary	Mandatory 4-module sequential flow with DTX/XSD validation	Module 1–4 sequential enforcement; SRN capture; schema validation	EUDAMED structured export	28 May 2026
UK	Market Routing	Single UK flow	GB (DORS) vs. NI (EUDAMED) explicit branch	Routing question; GMDN mandatory for GB; NI deduplication	DORS or EUDAMED export by route	28 May 2026
UK	GMDN Field	Optional/absent	Mandatory for GB DORS submissions	GMDN code field + validation	Included in DORS export	28 May 2026
Switzerland	swissdamed Module	Not present	New swissdamed module with Swiss-specific dataset	CHRN field; law-version branch; separate from EUDAMED	swissdamed package (separate from EU)	31 Dec 2026
Australia	UDI Section	Not present	Conditional UDI block for Class III/IIb MD	Class gate; Primary DI; issuing agency; AusUDID task; IVD exclusion	AusUDID data appended to TGA submission	Jun 2026
China	Classification Picker	Pre-2025-No.132 vocabulary	Updated catalogue with 31 reclassifications	Controlled vocab refresh; class recalculation; date-gated RF rule	Updated dossier route in NMPA package	4 Jan / 1 Apr 2026
Egypt	UDI Block	Not present	Structured Egyptian UDI block per EDA v02/2026	Primary DI; UDI-PIs; GMDN; 4 flag fields; Arabic fields conditional on lay-use	Egyptian UDI block in EDA submission	2026
Indonesia	Halal Section	Not present	Halal section for Class A MD from 18 Oct 2026	Class A gate; material origin; animal components; certificate OR exception upload	Halal documentation in BPJPH package	18 Oct 2026
Brazil	UDI/SIUD Dataset	Not present	Class-phased UDI dataset + SIUD linkage	Phase table lookup; Primary DI; UDI-PIs; SIUD link field; NOT universal from Mar 2026	SIUD-linked ANVISA submission	1 Mar 2026 (phased)
South Africa	Reliance Branch	Not present	Optional reliance pathway branch	Optional question; ref authority; foreign auth number; equivalence evidence upload	Reliance declaration in SAHPRA package	2026
South Africa	e-IFU Logic	Not present	Conditional e-IFU logic	Optional e-IFU question; URL; version; printed copy statement	e-IFU declaration in SAHPRA package	2026
USA (QMSR)	Quality System	QSR/QSIT labels + 21 CFR 820 refs	QMSR labels + ISO 13485:2016 + FDA addendum refs	Terminology replacement; ISO cert field → optional	Updated quality declaration in FDA export	Feb 2026

6. Recommended Release Sequence

The following release sequence is recommended to address regulatory changes in order of legal risk, effective date proximity, and engineering complexity.

Phase 1 — Critical / Immediate		Timing: Immediate — Q3 2026
EU — EUDAMED 4-Module Flow		Deadline: 28 May 2026
EUDAMED 4-module sequential integration, DTX/XSD schema, SRN capture. Already past effective date — urgent. Affects all EU MDR/IVDR submissions.		
UK — GB/NI Routing Split + GMDN		Deadline: 28 May 2026
Implement GB vs. NI routing branch. GMDN mandatory for GB DORS. Already past effective date — urgent.		
Canada — REP Builder		Deadline: 1 Apr 2026
REP XML builder, IMDRF TOC, CESC assembly. Already past effective date — urgent.		
USA — eSTAR v7.0 + HF Module		Deadline: 2026 / Jun 2026
v7.0 XFA parser per pathway, field ID migration, Human Factors module.		
Switzerland — swissdamed Module		Deadline: 31 Dec 2026
New swissdamed module with Swiss-specific dataset, CHRN field, law-version branching.		
Phase 2 — High Priority		Timing: Q2–Q3 2026
China — NMPA Classification Catalogue		Deadline: 4 Jan / 1 Apr 2026
Already past effective date. Load 31-item reclassification table, recalculate device class/route.		
Brazil — SIUD/UDI (Class-Phased)		Deadline: 1 Mar 2026 (phased)
SIUD operational. Implement class-phased UDI dataset + SIUD linkage. NOT universal.		
Australia — UDI Class III/IIb		Deadline: Jun 2026
Conditional UDI block for Class III/IIb MD. AusUDID post-approval task.		
Egypt — UDI Guideline v02/2026		Deadline: 2026
Egyptian UDI block: Primary DI, UDI-PIs, GMDN, flag fields, Arabic lay-use fields.		
South Africa — Reliance + e-IFU		Deadline: 2026
Optional reliance branch + conditional e-IFU logic. Both are optional branches.		
Indonesia — Halal (Class A)		Deadline: 18 Oct 2026
Halal section for Class A MD. Material origin, animal components, certificate/exception.		
Phase 3 — Content Updates		Timing: Q3–Q4 2026
USA — QMSR Terminology		Deadline: Feb 2026 (grace ended)

Replace QSR/QSIT with QMSR throughout. Update regulatory references. ISO cert field → optional.

Phase 4 — Watchlist Monitoring

Timing: Ongoing — Review Q4 2026

UAE — MOHAP → EDA Transfer

Deadline: Unconfirmed

Monitor for official instrument. No action until confirmed.

EU AI Act — Device Applicability

Deadline: Unconfirmed 2026

Device applicability scope not finalized. Monitor EC guidance.

Japan — PMDA eSubmission Expansion

Deadline: Scope unconfirmed

Monitor PMDA announcements. No wizard action until scope confirmed.

UK — MHRA Post-Brexit Reliance

Deadline: Still in consultation

Monitor MHRA consultation outcome. No action until guidance finalized.

FDA — Electronic Labeling NPRM

Deadline: Not yet final rule

Monitor Federal Register. No action until final rule published.

7. Watchlist

The following items are under active monitoring but have NOT been promoted to actionable priorities. No confirmed official instrument, final rule, or implementation guidance exists as of July 2026. These items must NOT be implemented in the wizard until officially confirmed. Review quarterly.

Item	Jurisdiction	Authority	Status	Trigger for Promotion	Review Frequency
UAE — MOHAP → EDA Authority Transfer	UAE	MOHAP / EDA	No official instrument confirmed	Official gazette notice or EDA announcement confirming transfer and new submission requirements	Quarterly
EU AI Act — Medical Device Applicability	EU	European Commission	Device applicability not finalized for 2026	EC guidance specifying AI Act requirements for medical device software (MDSW) in SB wizard context	Monthly
Japan — PMDA eSubmission Expansion	Japan	PMDA	Scope expansion to additional device classes unconfirmed	PMDA announcement specifying expanded eSubmission scope and system requirements	Quarterly
UK — MHRA Post-Brexit Reliance Framework	UK	MHRA	Still in consultation phase	Final MHRA guidance published on post-Brexit reliance pathway for device registrations	Monthly
USA — FDA Electronic Labeling NPRM	USA	FDA (CDRH)	Not yet a final rule (NPRM stage)	Final rule published in Federal Register with effective date and wizard-relevant requirements	Monthly

■■ **Policy Reminder:** Watchlist items must NOT be implemented in the Submission Builder wizard until an official instrument is confirmed. Premature implementation may create incorrect regulatory expectations for users. Escalate to regulatory team lead before any Watchlist item is promoted.

8. Sources & Official References

Jurisdiction	Authority	Document / Source	URL
USA — eSTAR v7.0	FDA	FDA eSTAR Electronic Submissions Gateway	https://www.fda.gov/medical-devices/how-study-and-market-your-device/electronic-submissions-gateway
USA — QMSR	FDA	FDA Quality Management System Regulation — 21 CFR Part 820	https://www.federalregister.gov/documents/2024/02/02/2024-01860/quality-management-system-regulation
Canada — REP	Health Canada	Regulatory Enrolment Process (REP) Program	https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/applications-submissions/regulatory-enrolment-process.html
EU — EUDAMED	European Commission	Regulation (EU) 2024/1860; EUDAMED Portal	https://ec.europa.eu/tools/eudamed
UK — GB/NI Routing	MHRA	Register Medical Devices to Place on the Market	https://www.gov.uk/guidance/register-medical-devices-to-place-on-the-market
Switzerland — swissdamed	Swissmedic	swissdamed Medical Device Registration Portal	https://www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/swissdamed.html
Australia — UDI	TGA	Unique Device Identification (UDI) — TGA UDI Compliance Timeframes v2.1	https://www.tga.gov.au/industry/medical-devices/unique-device-identification-udi
China — NMPA Classification	NMPA	NMPA Announcement 2025 No. 132 — Classification Catalogue Update	https://www.nmpa.gov.cn/
Egypt — UDI	EDA	EDA Regulatory Guideline on UDI for Medical Devices v02/2026	https://www.eda.gov.eg/
Indonesia — Halal	BPJPH / MoH	Government Regulation No. 42/2024; Ministry of Health Regulation No. 3/2024	https://bpjph.halal.go.id/
Brazil — SIUD	ANVISA	ANVISA RDC 591/2021 — UDI for Medical Devices; SIUD Portal	https://www.gov.br/anvisa/
South Africa — SAHPRA	SAHPRA	SAHPRA Medical Devices Reliance Guideline	https://www.sahpra.org.za/

This report was prepared using verified regulatory data as of July 2026. All regulatory requirements should be verified against the most current official authority publications prior to implementation. RegDesk assumes no liability for regulatory decisions made based on this report without independent verification.