

INTERNAL — REGULATORY INTELLIGENCE

Submission Builder Impact Assessment

May – July 2026 Regulatory Alert Review
SB Wizard Planning

Assessment date: July 29, 2026

Data cut-off: July 29, 2026 (July 30–31 not yet captured)

Alerts reviewed: 211 (207 from tracker + 4 missing alerts added)

Coverage: 64 markets

⚠ Methodology note: This report applies the two-field SB impact model. *Regulated-party impact* (what manufacturers must do) and *SB wizard impact* (what wizard changes are required) are assessed separately. A regulatory publication or deadline does not automatically require a wizard modification.



SB Action Dashboard

May 1 – July 29, 2026 | 211 alerts assessed across 64 markets

211

Total Alerts

0

P0 Release Blockers

36

P1 Confirmed Updates

65

P2 Scheduled Reviews

15

Watchlist

95

No SB Action

SB-Relevant Alerts by Impact Domain

Impact Domain	Count
Registration dossier	51
UDI/device registration	24
Product-specific technical evidence	15
Classification	8
Fees and admin	5
Import authorization	4
Clinical investigation	3
Labeling/IFU	3
Grouping	2
Variation/change notification	1

Key Metrics

Metric	Value
SB-relevant alerts (P1+P2)	101
Immediate action required (P1)	36
Scheduled review needed (P2)	65
Monitoring only (Watchlist)	15
No wizard action required	95
Missing alerts added	4
Reclassification corrections applied	6

P1 — Confirmed Updates Requiring Prompt Action

Alert ID	Country	Title	Priority	Action
Turkey_May 5, 2026, 11:02:29 AM	Turkey	Mandatory Use of the EUDAMED Database System (Law No. 2026/KKB-1) and ...	P1	Escalate for manual review
European Union_May 7, 2026, 4:49:31 AM	European Union	Implementing Regulation (EU) 2026/977 – Uniform Requirements for Confo...	P1	Implement now
Saudi Arabia_May 8, 2026, 10:49:12 AM	Saudi Arabia	SFDA Medical Devices Forms Updates	P1	Implement now
Switzerland_May 11, 2026, 4:55:35 AM	Switzerland	Swissdamed User Manual Actors	P1	Implement now
Malaysia_May 15, 2026, 4:32:33 AM	Malaysia	Requirements for Labelling of Medical Devices	P1	Implement now
Malaysia_May 15, 2026, 4:36:56 AM	Malaysia	Change Management for Registered Medical Devices	P1	Implement now

Serbia_May 19, 2026, 4:54:53 AM	Serbia	New Conditions and Methods of Recognition of Foreign Documents of Conf...	P1	Implement now
Serbia_May 19, 2026, 5:10:20 AM	Serbia	New Conditions and Methods of Recognition of Foreign Certificates of C...	P1	Implement now
Serbia_May 19, 2026, 5:12:59 AM	Serbia	New Conditions and Methods of Recognition of Foreign Documents of Conf...	P1	Implement now
Serbia_May 19, 2026, 5:15:08 AM	Serbia	New Conditions and Methods of Recognition of Foreign Certificates of C...	P1	Implement now
Serbia_May 19, 2026, 5:17:50 AM	Serbia	Instructions for Submitting a Request for Amendment/Additional Registr...	P1	Implement now
Mexico_May 19, 2026, 6:56:59 PM	Mexico	Cofepris has published Mexican Official Standard NOM-137-SSA1-2025 - L...	P1	Implement now

Executive Summary

Submission Builder Wizard Impact | May 1 – July 29, 2026

Key Finding: Of 211 regulatory alerts reviewed across 64 markets, **101 require Submission Builder wizard action (36 P1 + 65 P2)**. 15 alerts are on the Watchlist pending final publication. 95 alerts require no SB action — these are operational, fee, post-market, or manufacturer-facing compliance requirements that do not affect wizard content.

Critical distinction: Regulated-party urgency ≠ SB implementation urgency. Several high-urgency manufacturer deadlines (e.g. SUSAR reporting, UK annual fees, Denmark annual fees, EUDAMED for NBs and CAs) have *no SB wizard impact*.

P1 — Confirmed Updates (Implement Now)

- **FDA eSTAR Human Factors** — IVD and nIVD eSTAR wizards: new HF content, conditional logic, PDF/XML source re-association and export testing required before Aug 1, 2026
- **EU Implementing Regulation 2026/977** — Conformity assessment uniform requirements: MDR/IVDR conformity assessment wizard sections require review and update
- **EUDAMED mandatory (May 28)** — Confirm MDR/IVDR Basic UDI-DI, legacy device, SPP and actor registration wizard coverage; do not infer XSD change without technical spec review
- **Spain RECOPS** — Non-custom MD/IVD pathway migration: separate RECOPS portal from RPS (custom-made devices); update submission channel logic
- **Swissdamed mandatory (July 1)** — Map data dictionary; update MD/IVD/SPP/legacy/immediate-registration pathways, actor eligibility, and fee information
- **Serbia ALIMIS** — Multiple instruction documents updated to new revisions: registration (REV.6), expert opinion (REV.5), import (REV.3), clinical trial (VER.1)
- **Malaysia labelling (7th ed.)** — e-labelling risk assessment now mandatory for home-use devices; update labelling section
- **Malaysia change management** — Updated guidance: review variation wizard change categories and documentation requirements
- **Canada MDEL Phase 2** — Medical Device Establishment Licensing modernization: update MDEL wizard requirements and pathway logic
- **Mexico NOM-137-SSA1-2025** — Updated labelling standard: update Mexico wizard labelling section NOM reference and requirements
- **Saudi Arabia forms update** — SFDA updated application forms: replace source templates in Saudi Arabia wizard
- **South Africa RUO/IUO (GLF-MD-25A)** — Concrete form update: replace source template in SA wizard (validate form on SAHPRA site)
- **Malaysia online Product Classification (Aug 1)** — Fully online submission: update submission channel, pathway logic, attachment handling and output
- **Brazil UDI/SIUD operational** — UDI data submission now mandatory; update Brazil UDI wizard per NI 426/2026

P2 — Scheduled Reviews

65 alerts require scheduled review before next wizard release cycle. Key items include: Australia UDI guidance suite (multiple pages updated), Hong Kong listing guidance revisions (GN-00, GN-02, GN-06), Korea digital medical device and enforcement decree updates, Czech Republic custom-made device and FSC procedure updates, and Singapore grouping guidance (GN-12-1).

Watchlist

15 alerts are on the Watchlist — primarily China NMPA draft guidance documents (multiple product categories), Sweden AI supervision framework (developing), and UK consultation on proposed regulatory changes. **No SB action until final publication and regulatory delta confirmed.**

⚠ Report scope: Report issued July 29, 2026. July 30–31 data not yet captured. All confidence assessments are marked "Pending human validation." No conclusion regarding XML, XSD or generated-output changes should be made without reviewing applicable technical specifications

P1 — Confirmed Updates

36 alerts confirmed as requiring SB wizard implementation

Turkey_May 5, 2026, 11:02:29 AM | Turkey | European Commission / National CAs

P1

Mandatory Use of the EUDAMED Database System (Law No. 2026/KKB-1) and its Impact on the ÜTS Document and Device Registration Processes

Published: 5/4/2026 | Effective: 5/4/2026 | Type: Announcement

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		

Recommended Action **Escalate for manual review** **Confidence** High | *Pending human validation*

Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.

Official Source <https://www.titck.gov.tr/duyuru/2026-kkb-1-sayili-eudamed-veri-tabani-sistemini...>

European Union_May 7, 2026, 4:49:31 AM | European Union | European Commission / MDCG

P1

Implementing Regulation (EU) 2026/977 – Uniform Requirements for Conformity Assessment and Notified Bodies (Annex VII)

Published: 5/5/2026 | Effective: 5/4/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	EU Implementing Regulation 2026/977 on uniform requirements for conformity assessment — mandatory compliance for MDR/IVDR applications.		
SB Wizard Impact	Review EU MDR/IVDR conformity assessment wizard sections for alignment with IR 2026/977 uniform requirements; update assessment route options and documentation requirements.		
Regulatory Delta	New Implementing Regulation 2026/977 establishes uniform conformity assessment requirements — compare with current MDR/IVDR wizard content.		
Affected Wizard/Pathway	EU MDR conformity assessment wizard; EU IVDR conformity assessment wizard		

Recommended Action **Implement now** **Confidence** High | *Pending human validation*

Official Source https://eur-lex.europa.eu/eli/reg_impl/2026/977/oj

SFDA Medical Devices Forms Updates

Published: 5/5/2026 | Effective: 5/5/2026 | Type: Forms

Impact Domain	Registration dossier	Impact Category	Form/template update
Regulated-party Impact	SFDA has updated medical device application forms — submissions must use updated forms.		
SB Wizard Impact	Update Saudi Arabia MD registration wizard source templates with updated SFDA forms; verify all fields and attachments.		
Regulatory Delta	SFDA forms updated — field-level comparison required between current SB templates and new SFDA forms.		
Affected Wizard/Pathway	Saudi Arabia MD registration wizard — source form templates		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://sfda.gov.sa/en/forms?keys=&date%5Bmin%5D=&date%5Bmax%5D=&tags=3		

Swissdamed User Manual Actors

Published: 5/10/2026 | Effective: 5/10/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Product registration in Swissdamed mandatory from July 1, 2026 with transition through Dec 31, 2026. Note: this is NOT a blanket replacement of all previous reporting — scope varies by device type, actor eligibility and registration category.		
SB Wizard Impact	Map Swissdamed data dictionary and registration pathways; update: (1) MD/IVD/SPP new registration, (2) legacy device transitional registration, (3) immediate-registration exceptions (serious incidents, FSCAs, trends), (4) actor eligibility criteria, (5) per-UDI-DI fee information. M2M/REST API option for bulk submission may affect export format.		
Regulatory Delta	Previously: no mandatory Swissdamed product registration. Now: mandatory from July 1, 2026. Transition period to Dec 31, 2026. Immediate registration required for devices associated with serious incidents or FSCAs. Per-UDI-DI fees apply. Fee ordinance amended July 1, 2026.		
Affected Wizard/Pathway	Switzerland MD new registration; Switzerland IVD new registration; Switzerland SPP; Switzerland legacy device transition; Switzerland actor registration		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/bw...		

Requirements for Labelling of Medical Devices

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Labeling/IFU	Impact Category	Wizard content update
Regulated-party Impact	Updated Malaysia labelling guidance (7th edition) — manufacturers must comply with updated e-labelling requirements for home-use devices.		
SB Wizard Impact	Review Malaysia MD registration wizard for labelling section; update e-labelling option/risk assessment requirement if not currently reflected.		
Regulatory Delta	Previously: earlier labelling guidance edition. Now: 7th edition with e-labelling provisions for home-use devices. Risk assessment for e-labelling now mandatory.		
Affected Wizard/Pathway	Malaysia MD new registration wizard — labelling section		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://portal.mda.gov.my/index.php/ms/pengumuman/1800-revision-to-the-requireme...		

Change Management for Registered Medical Devices

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Variation/change notification	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Updated Malaysia change management guidance for registered medical devices.		
SB Wizard Impact	Review Malaysia variation/change notification wizard; update change categories, required documentation, and submission logic per updated guidance.		
Regulatory Delta	Updated change management guidance — compare with current wizard source document for delta.		
Affected Wizard/Pathway	Malaysia MD variation/change notification wizard		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://portal.mda.gov.my/index.php/ms/pengumuman/1799-publication-of-first-edit...		

New Conditions and Methods of Recognition of Foreign Documents of Conformity (Declaration of Conformity) in the Procedures Conducted before the Agency - Harmonization of National Regulations due to the Transition from EU Directives (MDD/AIMD) to EU Regulations (MDR)

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	ALIMs has updated submission instructions for MD registration, foreign document recognition, import of unregistered devices, and clinical trials — new versions published.		
SB Wizard Impact	Review Serbia MD registration wizard for alignment with updated ALIMs submission instructions (REV.6 for registration, REV.5 for expert opinion, REV.3 for import, VER.1 for clinical trials); update checklist, document requirements, and instructions.		
Regulatory Delta	Multiple ALIMs submission instruction documents updated to new versions — field-level comparison required.		
Affected Wizard/Pathway	Serbia MD new registration wizard; Serbia import (unregistered device) wizard; Serbia clinical investigation wizard		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.alims.gov.rs/wp-content/uploads/2026/05/1a.NOVI-uslovi-Declaration-o...		

New Conditions and Methods of Recognition of Foreign Certificates of Conformity of Medical Devices (EC Certificate) in the Procedures Conducted before the Agency - Harmonization of National Regulations due to the Transition from EU Directives (MDD/AIMD) to EU Regulations (MDR)

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	ALIMs has updated submission instructions for MD registration, foreign document recognition, import of unregistered devices, and clinical trials — new versions published.		
SB Wizard Impact	Review Serbia MD registration wizard for alignment with updated ALIMs submission instructions (REV.6 for registration, REV.5 for expert opinion, REV.3 for import, VER.1 for clinical trials); update checklist, document requirements, and instructions.		
Regulatory Delta	Multiple ALIMs submission instruction documents updated to new versions — field-level comparison required.		
Affected Wizard/Pathway	Serbia MD new registration wizard; Serbia import (unregistered device) wizard; Serbia clinical investigation wizard		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.alims.gov.rs/wp-content/uploads/2026/05/1b.NOVI-uslovi-ECsertifikata...		

New Conditions and Methods of Recognition of Foreign Documents of Conformity (Declaration of Conformity) in the Procedures Conducted before the Agency - Harmonization of National Regulations due to the Transition from EU Directives (IVDD) to EU Regulations (IVDR)

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	ALIMS has updated submission instructions for MD registration, foreign document recognition, import of unregistered devices, and clinical trials — new versions published.		
SB Wizard Impact	Review Serbia MD registration wizard for alignment with updated ALIMSSubmission instructions (REV.6 for registration, REV.5 for expert opinion, REV.3 for import, VER.1 for clinical trials); update checklist, document requirements, and instructions.		
Regulatory Delta	Multiple ALIMSSubmission instruction documents updated to new versions — field-level comparison required.		
Affected Wizard/Pathway	Serbia MD new registration wizard; Serbia import (unregistered device) wizard; Serbia clinical investigation wizard		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.alims.gov.rs/wp-content/uploads/2026/05/2a.NOVI-uslovi-Declaration-o...		

New Conditions and Methods of Recognition of Foreign Certificates of Conformity (EC Certificate) in the Procedures Conducted before the Agency - Harmonization of National Regulations due to the Transition from EU Directives (IVDD) to EU Regulations (IVDR)

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	ALIMS has updated submission instructions for MD registration, foreign document recognition, import of unregistered devices, and clinical trials — new versions published.		
SB Wizard Impact	Review Serbia MD registration wizard for alignment with updated ALIMSSubmission instructions (REV.6 for registration, REV.5 for expert opinion, REV.3 for import, VER.1 for clinical trials); update checklist, document requirements, and instructions.		
Regulatory Delta	Multiple ALIMSSubmission instruction documents updated to new versions — field-level comparison required.		
Affected Wizard/Pathway	Serbia MD new registration wizard; Serbia import (unregistered device) wizard; Serbia clinical investigation wizard		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.alims.gov.rs/wp-content/uploads/2026/05/2b.NOVI-uslovi-ECsertifikat-...		

Instructions for Submitting a Request for Amendment/Additional Registration of a Medical Device

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	ALIMS has updated submission instructions for MD registration, foreign document recognition, import of unregistered devices, and clinical trials — new versions published.		
SB Wizard Impact	Review Serbia MD registration wizard for alignment with updated ALIMs submission instructions (REV.6 for registration, REV.5 for expert opinion, REV.3 for import, VER.1 for clinical trials); update checklist, document requirements, and instructions.		
Regulatory Delta	Multiple ALIMs submission instruction documents updated to new versions — field-level comparison required.		
Affected Wizard/Pathway	Serbia MD new registration wizard; Serbia import (unregistered device) wizard; Serbia clinical investigation wizard		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.alims.gov.rs/wp-content/uploads/2026/05/4d.-Uputstvo_izmene_dopune_m...		

Cofepris has published Mexican Official Standard NOM-137-SSA1-2025 - Labeling of Medical Devices

Published: 5/19/2026 | Effective: 5/19/2027 | Type: Standard

Impact Domain	Labeling/IFU	Impact Category	Wizard content update
Regulated-party Impact	Mexico NOM-137-SSA1-2025 on labelling published — all medical devices sold in Mexico must comply with updated labelling standard.		
SB Wizard Impact	Review Mexico MD wizard labelling section; update NOM reference and labelling requirements per NOM-137-SSA1-2025.		
Regulatory Delta	Previously: NOM-137 previous version. Now: NOM-137-SSA1-2025 published — compare labelling requirements for delta.		
Affected Wizard/Pathway	Mexico MD new registration wizard — labelling section		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://diariooficial.gob.mx/nota_detalle.php?codigo=5787790&fecha=19/05/2026#gs...		

Operationalization of EUDAMED on May 28, 2026

Published: 5/20/2026 | Effective: 5/28/2026 | Type: Circular

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation

⚠️ **Note:** Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.

Official Source <https://www.infarmed.pt/documents/15786/12277909/Operacionaliza%C3%A7%C3%A3o+da+...>

Registration of Invoicing Details for Economic Operators Registered in Eudamed

Published: 5/26/2026 | Effective: | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://www.lakemedelsverket.se/sv/blanketter/registrera-faktureringsuppgifter--...		

Launch of RECOPS, the New Application for the Marketing Registration of Medical Devices

Published: 5/27/2026 | Effective: 6/15/2026 | Type: Notification

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Non-custom-made MDs and IVDs must use RECOPS for new marketing registrations. IMPORTANT: Custom-made devices continue through RPS — NOT covered by RECOPS.		
SB Wizard Impact	Separate Spain MD, IVD, and custom-made pathways in SB wizard; update submission channel to RECOPS for non-custom MDs/IVDs; verify portal fields, labeling/IFU upload requirements, device identifiers, applicant information; add custom-made exception logic.		
Regulatory Delta	Previously: marketing registrations via legacy AEMPS portal. Now: non-custom MD/IVD new registrations via RECOPS. Custom-made devices remain via RPS. Scope: non-custom-made medical devices and IVDs only.		
Affected Wizard/Pathway	Spain MD new registration wizard; Spain IVD new registration wizard (RECOPS pathway); custom-made device wizard (RPS — unchanged)		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.aemps.gob.es/informa/puesta-en-marcha-de-recops-la-nueva-aplicacion-...		

Registration

Published: 5/28/2026 | Effective: 5/28/2026 | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://laegemiddelstyrelsen.dk/da/udstyr/registrering/		

Registration in Eudamed

Published: 5/28/2026 | Effective: 5/28/2026 | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://laegemiddelstyrelsen.dk/da/nyheder/senest-opdaterede-indhold/~media/CBC...		

EUDAMED: Clarifications Regarding Obligations as of 28 May 2026

Published: 5/28/2026 | Effective: 5/28/2026 | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://www.fagg.be/nl/news/eudamed_verduidelijkingen_over_de_verplichtingen_van...		

eSTAR Program

Published: 6/1/2026 | Effective: 8/1/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update + Export/XML update
Regulated-party Impact	Must use updated eSTAR v7 with Human Factors guidance content from Aug 1, 2026.		
SB Wizard Impact	IVD and nIVD eSTAR wizards require: (1) new HF question content, (2) conditional logic updates for HF sections, (3) PDF/XML source file re-association to eSTAR v7, (4) end-to-end export testing before Aug 1 release.		
Regulatory Delta	Previously: eSTAR v6.x without mandatory HF guidance content. Now: eSTAR v7 incorporates Human Factors Information guidance (FDA-2023-D-2734) content; effective Aug 1, 2026 for all new and pending submissions.		
Affected Wizard/Pathway	FDA 510(k) IVD eSTAR wizard; FDA 510(k) nIVD eSTAR wizard; De Novo pathways using eSTAR		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.fda.gov/medical-devices/how-study-and-market-your-device/estar-progr...		

Swissdamed Business Rules

Published: 6/2/2026 | Effective: 6/2/2026 | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/bw...		

European Database for Medical Devices: EUDAMED

Published: 5/28/2026 | Effective: 5/28/2026 | Type: News

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://www.bfarm.de/DE/Medizinprodukte/Ueberblick/Europa-und-EUDAMED/EUDAMED/ a...		

May 28, 2026: Initial and Amendment Notification MP and IVD

Published: 5/28/2026 | Effective: 5/28/2026 | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte/DMIDS-anleitung-anz...		

Swissdamed Machine-to-Machine REST API Technical Documentation

Published: 6/8/2026 | Effective: 6/5/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Product registration in Swissdamed mandatory from July 1, 2026 with transition through Dec 31, 2026. Note: this is NOT a blanket replacement of all previous reporting — scope varies by device type, actor eligibility and registration category.		
SB Wizard Impact	Map Swissdamed data dictionary and registration pathways; update: (1) MD/IVD/SPP new registration, (2) legacy device transitional registration, (3) immediate-registration exceptions (serious incidents, FSCAs, trends), (4) actor eligibility criteria, (5) per-UDI-DI fee information. M2M/REST API option for bulk submission may affect export format.		
Regulatory Delta	Previously: no mandatory Swissdamed product registration. Now: mandatory from July 1, 2026. Transition period to Dec 31, 2026. Immediate registration required for devices associated with serious incidents or FSCAs. Per-UDI-DI fees apply. Fee ordinance amended July 1, 2026.		
Affected Wizard/Pathway	Switzerland MD new registration; Switzerland IVD new registration; Switzerland SPP; Switzerland legacy device transition; Switzerland actor registration		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/bw...		

EUDAMED, The European Database for Medical Devices, Launches

Published: 5/28/2026 | Effective: 5/28/2026 | Type: News notification

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://www.zva.gov.lv/lv/jaunumi-un-publikacijas/jaunumi/darbu-sak-eiropas-medi...		

Mandatory use of EUDAMED from May 28, 2026

Published: 5/28/2026 | Effective: 5/28/2026 | Type: Medical Device news

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://santesecu.public.lu/fr/espace-professionnel/departement-sante/pharmacies...		

Phase 2 of our Work to Modernize Medical Device Establishment Licensing

Published: 6/17/2026 | Effective: 12/14/2026 | Type: Bulletin

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Health Canada Phase 2 modernization of Medical Device Establishment Licensing — updated MDEL requirements.		
SB Wizard Impact	Review Canada MDEL wizard for updated licensing requirements; update pathway logic, required documents, and submission instructions per Phase 2 changes.		
Regulatory Delta	Phase 2 MDEL modernization — compare new requirements with current SB wizard content.		
Affected Wizard/Pathway	Canada Medical Device Establishment Licence (MDEL) wizard		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance...		

Standard Specification Annex No. (1) of the Technical Regulation for Communications and Information Technology Devices Update

Published: 6/18/2026 | Effective: 11/1/2026 | Type: Announcement

Impact Domain	Registration dossier	Impact Category	Form/template update
Regulated-party Impact	SFDA has updated medical device application forms — submissions must use updated forms.		
SB Wizard Impact	Update Saudi Arabia MD registration wizard source templates with updated SFDA forms; verify all fields and attachments.		
Regulatory Delta	SFDA forms updated — field-level comparison required between current SB templates and new SFDA forms.		
Affected Wizard/Pathway	Saudi Arabia MD registration wizard — source form templates		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://drive.google.com/file/d/10dstW9MxHscAWGiYnmxCNleQ4ozwVuA6/view?usp=shari...		

Swissdamed User Manual Actors

Published: 6/18/2026 | Effective: 6/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Product registration in Swissdamed mandatory from July 1, 2026 with transition through Dec 31, 2026. Note: this is NOT a blanket replacement of all previous reporting — scope varies by device type, actor eligibility and registration category.		
SB Wizard Impact	Map Swissdamed data dictionary and registration pathways; update: (1) MD/IVD/SPP new registration, (2) legacy device transitional registration, (3) immediate-registration exceptions (serious incidents, FSCAs, trends), (4) actor eligibility criteria, (5) per-UDI-DI fee information. M2M/REST API option for bulk submission may affect export format.		
Regulatory Delta	Previously: no mandatory Swissdamed product registration. Now: mandatory from July 1, 2026. Transition period to Dec 31, 2026. Immediate registration required for devices associated with serious incidents or FSCAs. Per-UDI-DI fees apply. Fee ordinance amended July 1, 2026.		
Affected Wizard/Pathway	Switzerland MD new registration; Switzerland IVD new registration; Switzerland SPP; Switzerland legacy device transition; Switzerland actor registration		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/bw...		

New Options for Product Registration in Swissdamed: Online Editor and M2M Interface, and Registration of Master UDI-DI

Published: 6/19/2026 | Effective: | Type: Notification

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Product registration in Swissdamed mandatory from July 1, 2026 with transition through Dec 31, 2026. Note: this is NOT a blanket replacement of all previous reporting — scope varies by device type, actor eligibility and registration category.		
SB Wizard Impact	Map Swissdamed data dictionary and registration pathways; update: (1) MD/IVD/SPP new registration, (2) legacy device transitional registration, (3) immediate-registration exceptions (serious incidents, FSCAs, trends), (4) actor eligibility criteria, (5) per-UDI-DI fee information. M2M/REST API option for bulk submission may affect export format.		
Regulatory Delta	Previously: no mandatory Swissdamed product registration. Now: mandatory from July 1, 2026. Transition period to Dec 31, 2026. Immediate registration required for devices associated with serious incidents or FSCAs. Per-UDI-DI fees apply. Fee ordinance amended July 1, 2026.		
Affected Wizard/Pathway	Switzerland MD new registration; Switzerland IVD new registration; Switzerland SPP; Switzerland legacy device transition; Switzerland actor registration		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte/medizinprodukte-dat...		

Procurement of Medical Devices in Healthcare Facilities

Published: 6/19/2026 | Effective: 5/19/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Product registration in Swissdamed mandatory from July 1, 2026 with transition through Dec 31, 2026. Note: this is NOT a blanket replacement of all previous reporting — scope varies by device type, actor eligibility and registration category.		
SB Wizard Impact	Map Swissdamed data dictionary and registration pathways; update: (1) MD/IVD/SPP new registration, (2) legacy device transitional registration, (3) immediate-registration exceptions (serious incidents, FSCAs, trends), (4) actor eligibility criteria, (5) per-UDI-DI fee information. M2M/REST API option for bulk submission may affect export format.		
Regulatory Delta	Previously: no mandatory Swissdamed product registration. Now: mandatory from July 1, 2026. Transition period to Dec 31, 2026. Immediate registration required for devices associated with serious incidents or FSCAs. Per-UDI-DI fees apply. Fee ordinance amended July 1, 2026.		
Affected Wizard/Pathway	Switzerland MD new registration; Switzerland IVD new registration; Switzerland SPP; Switzerland legacy device transition; Switzerland actor registration		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/mu...		

Swissdamed User Guide - Playground

Published: 6/19/2026 | Effective: 6/19/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Product registration in Swissdamed mandatory from July 1, 2026 with transition through Dec 31, 2026. Note: this is NOT a blanket replacement of all previous reporting — scope varies by device type, actor eligibility and registration category.		
SB Wizard Impact	Map Swissdamed data dictionary and registration pathways; update: (1) MD/IVD/SPP new registration, (2) legacy device transitional registration, (3) immediate-registration exceptions (serious incidents, FSCAs, trends), (4) actor eligibility criteria, (5) per-UDI-DI fee information. M2M/REST API option for bulk submission may affect export format.		
Regulatory Delta	Previously: no mandatory Swissdamed product registration. Now: mandatory from July 1, 2026. Transition period to Dec 31, 2026. Immediate registration required for devices associated with serious incidents or FSCAs. Per-UDI-DI fees apply. Fee ordinance amended July 1, 2026.		
Affected Wizard/Pathway	Switzerland MD new registration; Switzerland IVD new registration; Switzerland SPP; Switzerland legacy device transition; Switzerland actor registration		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/bw...		

User Manual Swissdamed UDI Device Module

Published: 6/19/2026 | Effective: 6/19/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Product registration in Swissdamed mandatory from July 1, 2026 with transition through Dec 31, 2026. Note: this is NOT a blanket replacement of all previous reporting — scope varies by device type, actor eligibility and registration category.		
SB Wizard Impact	Map Swissdamed data dictionary and registration pathways; update: (1) MD/IVD/SPP new registration, (2) legacy device transitional registration, (3) immediate-registration exceptions (serious incidents, FSCAs, trends), (4) actor eligibility criteria, (5) per-UDI-DI fee information. M2M/REST API option for bulk submission may affect export format.		
Regulatory Delta	Previously: no mandatory Swissdamed product registration. Now: mandatory from July 1, 2026. Transition period to Dec 31, 2026. Immediate registration required for devices associated with serious incidents or FSCAs. Per-UDI-DI fees apply. Fee ordinance amended July 1, 2026.		
Affected Wizard/Pathway	Switzerland MD new registration; Switzerland IVD new registration; Switzerland SPP; Switzerland legacy device transition; Switzerland actor registration		
Recommended Action	Implement now	Confidence	High Pending human validation
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/bw...		

MDCG Position Paper: Management of SS(C)P in EUDAMED after mandatory use

Published: 6/18/2026 | Effective: | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	Manufacturers and authorised representatives must register actors and devices in EUDAMED as of May 28, 2026. Market surveillance and NB/certificate modules apply primarily to CAs and NBs respectively.		
SB Wizard Impact	Confirm MDR and IVDR wizard coverage: (1) Basic UDI-DI + first UDI-DI registration (MDR Art. 29, IVDR Art. 26), (2) legacy MD/IVD device registration, (3) SPP registrations, (4) actor/SRN field in wizard. Do NOT infer XSD/data-model change solely from mandatory-use date — technical spec review required.		
Regulatory Delta	Previously: EUDAMED voluntary. Now: mandatory for actors, UDI/device data, NB/certificates, market surveillance from May 28, 2026. "Replaces national registration databases" should NOT be stated globally — varies by member state.		
Affected Wizard/Pathway	EU MDR Basic UDI-DI wizard; IVDR Basic UDI-DI wizard; MDR/IVDR legacy device registration; SPP wizard; Actor registration		
Recommended Action	Escalate for manual review	Confidence	High Pending human validation
⚠️ Note: Country-specific variations: Denmark, Germany, Belgium, Portugal, Sweden, Luxembourg, Latvia, Slovenia all have separate alerts — consolidate into single EUDAMED implementation review.			
Official Source	https://health.ec.europa.eu/document/download/a80332cf-e9f0-4d45-8863-3d96e8c2a6...		

Communication on Research Use Only (RUO) and Investigational Use Only (IUO) Medical Devices including In Vitro Diagnostic Devices (IVDs)

Published: 6/25/2026 | Effective: 6/25/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	SAHPRA communication on RUO/IUO medical devices — manufacturers must comply with updated requirements for RUO/IUO device communications and any associated form (GLF-MD-25A).		
SB Wizard Impact	Replace current RUO/IUO source template with updated form/guidance; verify all form fields and attachments match updated SAHPRA requirements. If GLF-MD-25A is referenced, update to this specific form version.		
Regulatory Delta	Previously: earlier SAHPRA RUO/IUO guidance/form. Now: updated communication with possible new form GLF-MD-25A — requires form comparison to confirm field-level changes.		
Affected Wizard/Pathway	South Africa RUO/IUO device wizard (if exists); South Africa general MD registration wizard — RUO/IUO exception pathway		
Recommended Action	Implement now	Confidence	Medium Pending human validation
⚠️ Note: MISSING ALERT ADDED: GLF-MD-25A is a concrete form update — verify specific form version against SAHPRA document library.			
Official Source	https://www.sahpra.org.za/document/communication-on-research-use-only-ruo-and-in...		

Fully Online Product Classification Application (effective Aug 1, 2026)

Published: 2026-05-01 (est.) | Effective: 2026-08-01 | Type: Announcement

Impact Domain	Classification	Impact Category	Conditional logic or pathway update
Regulated-party Impact	All Product Classification applications must be submitted fully online from Aug 1, 2026 — no paper submissions accepted.		
SB Wizard Impact	Update Malaysia Product Classification wizard submission channel; review new/renewal pathway logic, repeatable product handling, attachment requirements, fee structure, and output instructions for online-only flow.		
Regulatory Delta	Previously: paper or hybrid submission accepted. Now: fully online from Aug 1, 2026. Affects new registration, renewal, and variation pathways.		
Affected Wizard/Pathway	Malaysia Product Classification wizard; Malaysia MD new registration wizard (if classification is a prerequisite step)		
Recommended Action	Implement now	Confidence	High Pending human validation
⚠️ Note: MISSING ALERT — not in spreadsheet but confirmed by MDA announcement.			
Official Source	https://www.mda.gov.my		

GLF-MD-25A: Updated RUO/IUO Application Form

Published: 2026-06-01 (est.) | Effective: 2026-06-01 (est.) | Type: Application Form

Impact Domain	Registration dossier	Impact Category	Form/template update
Regulated-party Impact	Applications for Research Use Only (RUO) and Investigational Use Only (IUO) medical devices must use updated SAHPRA form GLF-MD-25A.		
SB Wizard Impact	Replace current RUO/IUO source template with GLF-MD-25A; verify all form fields, attachments, and workflow steps match updated version. This is a concrete form update, not just a general communication.		
Regulatory Delta	Previously: earlier SAHPRA RUO/IUO form version. Now: GLF-MD-25A published — field-level comparison required with current SB template.		
Affected Wizard/Pathway	South Africa RUO/IUO device wizard (if exists); South Africa MD registration wizard — RUO/IUO exception pathway		
Recommended Action	Implement now	Confidence	Medium Pending human validation
⚠️ Note: MISSING ALERT — GLF-MD-25A is a concrete form update per SAHPRA document library. Validate form version on SAHPRA site before implementation.			
Official Source	https://www.sahpra.org.za/document-library/		

P2 — Scheduled Reviews

65 alerts requiring scheduled review before next wizard release

Malaysia_May 4, 2026, 4:14:21 AM | Malaysia | MDA

P2

Joint Announcement by Medical Device Authority (MDA) Malaysia and Thai Food and Drug Administration (Thai FDA) on Full Implementation of the Medical Device Regulatory Reliance Programme

Published: 5/1/2026 | Effective: 5/1/2026 | Type: Notification

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Joint Malaysia-Thailand regulatory announcement — review for bilateral market applicability.		
SB Wizard Impact	Review for impact on Malaysia or Thailand wizard content; update references if specific regulatory changes identified.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://portal.mda.gov.my/index.php/ms/pengumuman/1795-joint-announcement-by-med...		

Australia_May 6, 2026, 5:47:00 AM | Australia | TGA

P2

Accessing and using the AusUDID

Published: 5/4/2026 | Effective: N/A | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/products/medical-devices/labelling-and-advertising/unique...		

AusUDID submission methods

Published: 5/4/2026 | Effective: N/A | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/products/medical-devices/labelling-and-advertising/unique...		

Accessing the AusUDID

Published: 5/4/2026 | Effective: N/A | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/resources/resources/user-guide/accessing-ausudid		

AusUDID data elements

Published: 5/4/2026 | Effective: N/A | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/products/medical-devices/labelling-and-advertising/unique...		

Guidance on Bundling Criteria for Medical Devices within a Single MDMA Application (MDS – G028)

Published: 5/5/2026 | Effective: 5/5/2026 | Type: Guidance

Impact Domain	Grouping	Impact Category	Conditional logic or pathway update
Regulated-party Impact	SFDA guidance on bundling criteria for medical devices within a single MDMA application.		
SB Wizard Impact	Review Saudi Arabia grouping/bundling wizard logic; update bundling eligibility criteria per SFDA guidance.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	Saudi Arabia MD registration — bundling/grouping section		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://sfda.gov.sa/en/taxonomy/term/3		

Patient-Matched Guides for Orthopedic Implants

Published: 5/6/2026 | Effective: 5/7/2026 | Type: Guidance

Impact Domain	Product-specific technical evidence	Impact Category	Wizard content update
Regulated-party Impact	Manufacturers of patient-matched guides must follow new FDA guidance for orthopedic implants.		
SB Wizard Impact	Review FDA 510(k) nIVD wizard for patient-matched device questions; update if product-specific guidance content is missing.		
Regulatory Delta	New FDA guidance on patient-matched orthopedic implant guides — review against current wizard content.		
Affected Wizard/Pathway	FDA 510(k) nIVD wizard — patient-matched/custom devices		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient...		

Information Sheet Combined Studies

Published: 5/1/2026 | Effective: 5/1/2026 | Type: Guidance

Impact Domain	Clinical investigation	Impact Category	Wizard content update
Regulated-party Impact	Updated information sheet for combined/performance studies of IVDs in Switzerland.		
SB Wizard Impact	Review Switzerland clinical investigation wizard for updated combined-study and IVD performance study guidance; update instructions or document checklists if affected.		
Regulatory Delta	Updated information sheets — compare against current wizard source documents.		
Affected Wizard/Pathway	Switzerland clinical investigation / IVD performance study wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizinprodukte/mep_urr/bw...		

TCOKKA - Publication of Implementing Regulation (EU) 2026/977 on Common Requirements for Notified Bodies and Conformity Assessment (MDR-IVDR Annex VII) by the European Commission

Published: 5/7/2026 | Effective: Not Announced | Type: Announcement

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Turkey regulatory update — review for applicability.		
SB Wizard Impact	Review Turkey wizard for updated regulatory references.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.titck.gov.tr/duyuru/tcokka-avrupa-komisyonunca-onaylanmis-kuruluslar...		

Using assessments from comparable overseas regulators for medical devices

Published: 5/11/2026 | Effective: N/A | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Updated TGA guidance on using overseas regulatory assessments — expanded pathways for comparable regulator evidence.		
SB Wizard Impact	Review Australia wizard comparable-regulator pathway logic; update eligible regulator list and evidence requirements per updated TGA guidance.		
Regulatory Delta	Updated guidance on market authorisation evidence from comparable regulators — review current wizard against updated TGA document.		
Affected Wizard/Pathway	Australia MD/IVD registration wizard — comparable regulator pathway		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/resources/guidance/using-assessments-comparable-overseas-...		

Use of market authorisation evidence from comparable overseas regulators and assessment bodies for medical devices (including IVDs)

Published: 5/11/2026 | Effective: N/A | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/resources/guidance/use-market-authorisation-evidence-comp...		

Note No. 41 to Pharmaceutical Establishment and Economic Operators Relating to Requests for Classification of Products

Published: 5/10/2026 | Effective: 5/10/2026 | Type: Notice

Impact Domain	Classification	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Algeria classification request procedure — updated requirements for device classification submissions.		
SB Wizard Impact	Review Algeria classification wizard; update classification request procedure and documentation requirements.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://drive.google.com/file/d/1oqkumGkZqFPWEfUdLA8nkXH8e1aJQlu_/view?usp=shari...		

Note No. 42 to Pharmaceutical Establishment Relating to Requests for Classification of Products

Published: 5/11/2026 | Effective: 5/11/2026 | Type: Notice

Impact Domain	Classification	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Algeria classification request procedure — updated requirements for device classification submissions.		
SB Wizard Impact	Review Algeria classification wizard; update classification request procedure and documentation requirements.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://drive.google.com/file/d/18bQPUjjwVZSPdJOU3HPKIs8mp5OEWBMO/view?usp=shari...		

GN-00: Definitions and Abbreviations for the Medical Device Administrative Control System

Published: 5/13/2026 | Effective: 5/13/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	Monitor for applicability.		
SB Wizard Impact	Review Hong Kong wizard definitions and abbreviations section; update if terminology has changed in updated guidance GN-00.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.mdd.gov.hk/filemanager/common/mdacs/GN-00-E.pdf		

Guidelines for Registration Processes of Medical Devices in the Product Tracking System

Published: 5/13/2026 | Effective: 5/13/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Turkey regulatory update — review for applicability.		
SB Wizard Impact	Review Turkey wizard for updated regulatory references.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.titck.gov.tr/duyuru/tibbi-cihazlarin-urun-takip-sistemine-kayit-sure...		

Medical Devices: Conformity Assessment and the UKCA Mark

Published: 5/13/2026 | Effective: 5/13/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	Updated MHRA guidance on conformity assessment and UKCA mark.		
SB Wizard Impact	Review UK MD/IVD wizard for conformity assessment pathway options and UKCA mark requirements; update if guidance version referenced in wizard is superseded.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gov.uk/guidance/medical-devices-conformity-assessment-and-the-ukca-m...		

Preparing for an application audit for in-vitro diagnostic medical devices

Published: 5/12/2026 | Effective: N/A | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/resources/guidance/preparing-application-audit-vitro-diag...		

ARCSA has published Resolution ARCSA-DE-2026-003-DASP - Technical Health Regulations for Obtaining Medical Device Registration

Published: 5/18/2026 | Effective: 1/28/2027 | Type: Resolution

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Ecuador registration/licensing update — review for wizard applicability.		
SB Wizard Impact	Review Ecuador wizard for updated registration requirements; assess impact on dossier content.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://esacc.corteconstitucional.gob.ec/storage/api/v1/10_DWL_FL/eyJYXJwZXRhIj...		

User Guide for Requesting the Issuance of a Registration Certificate and Related Procedures

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Nicaragua registration/licensing update — review for wizard applicability.		
SB Wizard Impact	Review Nicaragua wizard for updated registration requirements; assess impact on dossier content.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.minsa.gob.ni/sites/default/files/publicaciones/M1-C-CON-DRES-DRPT-G0...		

New Official Request Form for Health Registration Certificates and Signature Validation of Health Professionals and Technicians.

Published: 5/15/2026 | Effective: 5/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Nicaragua registration/licensing update — review for wizard applicability.		
SB Wizard Impact	Review Nicaragua wizard for updated registration requirements; assess impact on dossier content.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.minsa.gob.ni/sites/default/files/publicaciones/FORMATO%20OFICIAL%20D...		

China NMPA Issues Guidance on Registration Review for Percutaneous Coronary Intervention Physiological Function Detection Devices

Published: 5/8/2026 | Effective: 5/8/2026 | Type: Guidance

Impact Domain	Product-specific technical evidence	Impact Category	Wizard content update
Regulated-party Impact	NMPA technical review guidance update — device-specific registration requirements updated.		
SB Wizard Impact	Review China wizard for product-specific technical sections affected by updated NMPA registration review guidelines.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.cmde.org.cn/xwdt/shpgzg/gztg/20260508154726128.html		

Clinical Investigations for Medical Devices

Published: 5/14/2026 | Effective: 5/14/2026 | Type: Guidance

Impact Domain	Clinical investigation	Impact Category	Wizard content update
Regulated-party Impact	Updated MHRA clinical investigation submission guidance including IRAS form requirements and supporting document list.		
SB Wizard Impact	Review UK clinical investigation wizard for IRAS form integration; update supporting document checklist per updated MHRA guidance.		
Regulatory Delta	Previously: MHRA clinical investigation guidance pre-update. Now: updated guidance with revised IRAS form and supporting documents. Exact delta requires document comparison.		
Affected Wizard/Pathway	UK Clinical Investigation / CTIMP wizard (if in scope)		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gov.uk/guidance/notify-mhra-about-a-clinical-investigation-for-a-med...		

Application for Authorization to place a Medical Device on the Market in the Czech Republic, Put it into Service and Use it

Published: 5/18/2026 | Effective: 5/18/2026 | Type: Notification

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Czech Republic application process for placing MD on market — updated requirements.		
SB Wizard Impact	Review Czech Republic MD market authorization wizard; update requirements per updated notification.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://sukl.gov.cz/pokyny-ustavu/pokyny-zdravotnicke-prostredky/zp-26-verze-1/		

ANVISA Launches DUIMP Queue Dashboard and Issues Guidance on Filing Compliance for Importers

Published: 5/19/2026 | Effective: 5/19/2026 | Type: Circular

Impact Domain	Import authorization	Impact Category	Instructions/reference update only
Regulated-party Impact	Updated ANVISA DUIMP importation guidance — importers must follow updated v1.9 procedures.		
SB Wizard Impact	Review Brazil import wizard for updated DUIMP procedures; update instructions and references to guidance version 1.9.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/anvisa-divulga-pai...		

Importation No. 048/2026

Published: 5/21/2026 | Effective: 5/21/2026 | Type: Circular

Impact Domain	Import authorization	Impact Category	Instructions/reference update only
Regulated-party Impact	Updated ANVISA DUIMP importation guidance — importers must follow updated v1.9 procedures.		
SB Wizard Impact	Review Brazil import wizard for updated DUIMP procedures; update instructions and references to guidance version 1.9.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gov.br/siscomex/pt-br/noticias/noticias-siscomex-importacao/Comunica...		

Complying with the Unique Device Identification timeframes for medical devices

Published: 5/22/2026 | Effective: N/A | Type: guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/resources/guidance/complying-unique-device-identification...		

Preparing for an application audit for in-vitro diagnostic medical devices

Published: 5/12/2026 | Effective: N/A | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/resources/guidance/preparing-application-audit-vitro-diag...		

Methodological Instructions for Submitting an Application for a Free Sale Certificate (FSC) for Medical Devices

Published: 5/18/2026 | Effective: 5/28/2026 | Type: Notification

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Czech SÚKL updated FSC application process — temporary retention through RZPRO system or updated methodological instructions.		
SB Wizard Impact	Review Czech FSC wizard for updated submission channel and instructions.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://sukl.gov.cz/pokyny-ustavu/pokyny-zdravotnicke-prostredky/zp-27-verze-1/		

Approval and Review Procedures for New Technology Medical Devices

Published: 5/26/2026 | Effective: 5/26/2026 | Type: Guidance for officials

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Korea MFDS regulatory update.		
SB Wizard Impact	Review Korea wizard for updated regulatory references.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.mfds.go.kr/brd/m_1059/view.do?seq=15241&srchFr=&srchTo=&srchWord=&sr...		

FAQs for Medical Device Non-clinical Trials Guidance

Published: 5/28/2026 | Effective: 5/28/2026 | Type: Guidance

Impact Domain	Product-specific technical evidence	Impact Category	Wizard content update
Regulated-party Impact	Updated Korea non-clinical testing guidance for medical devices.		
SB Wizard Impact	Review Korea MD registration wizard for non-clinical test evidence section; update content per updated MFDS non-clinical guidance.		
Regulatory Delta	Updated non-clinical testing guidance — compare with current wizard source.		
Affected Wizard/Pathway	Korea MD new registration wizard — non-clinical evidence section		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
⚠️ Note: RECLASSIFIED: Non-clinical testing → Product-specific technical evidence (previously misclassified as Post-market/vigilance).			
Official Source	https://www.mfds.go.kr/brd/m_1060/view.do?seq=15861&srchFr=&srchTo=&srchWord=&sr...		

Temporary Retention of FSC Applications through RZPRO

Published: 5/27/2026 | Effective: | Type: Notification

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Czech SÚKL updated FSC application process — temporary retention through RZPRO system or updated methodological instructions.		
SB Wizard Impact	Review Czech FSC wizard for updated submission channel and instructions.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://sukl.gov.cz/zdravotnicke-prostredky/aktuality-zp/docasne-zachovani-podav...		

Guidance: Importation via DUIMP_v1.9

Published: 6/1/2026 | Effective: 6/1/2026 | Type: Guidance

Impact Domain	Import authorization	Impact Category	Instructions/reference update only
Regulated-party Impact	Updated ANVISA DUIMP importation guidance — importers must follow updated v1.9 procedures.		
SB Wizard Impact	Review Brazil import wizard for updated DUIMP procedures; update instructions and references to guidance version 1.9.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicacoes/portos-aeroportos...		

Methodological Guideline for the Implementation of MDR Requirements for Custom-Made Devices in Dental Laboratories

Published: 6/1/2026 | Effective: 6/1/2026 | Type: Guideline

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Czech SÚKL methodological guideline on MDR requirements for custom-made devices.		
SB Wizard Impact	Review Czech Republic custom-made device wizard; update MDR compliance pathway and documentation requirements per updated methodological guideline.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	Czech Republic custom-made device wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://sukl.gov.cz/pokyny-ustavu/pokyny-zdravotnicke-prostredky/zp-28-verze-1/		

GN-12-1: Guidance on Grouping of Medical Devices for Product Registration – General Grouping Criteria

Published: 6/2/2026 | Effective: 6/2/2026 | Type: Guidance

Impact Domain	Grouping	Impact Category	Conditional logic or pathway update
Regulated-party Impact	HSA updated guidance on grouping of medical devices for product registration.		
SB Wizard Impact	Review Singapore MD grouping wizard; update grouping criteria and logic per updated HSA guidance GN-12-1.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	Singapore MD grouping wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.hsa.gov.sg/medical-devices/guidance-documents/#toggle=togglepanel-pr...		

Regulatory Requirements for Medical Devices Electronic Instructions for Use (e-IFU)

Published: 6/4/2026 | Effective: 6/4/2026 | Type: Guidance

Impact Domain	Labeling/IFU	Impact Category	Wizard content update
Regulated-party Impact	SAHPRA guidance on electronic IFU (e-IFU) for medical devices — manufacturers must comply with e-IFU requirements.		
SB Wizard Impact	Review South Africa MD wizard labelling/IFU section; add e-IFU option and eligibility criteria if not currently present.		
Regulatory Delta	New SAHPRA e-IFU guidance — compare with current wizard labelling section.		
Affected Wizard/Pathway	South Africa MD registration wizard — labelling/IFU section		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.sahpra.org.za/document/regulatory-requirements-for-medical-devices-e...		

Departmental regulatory legal act on the procedure for conducting inspection control of production conditions of medical devices during their state registration # 3838 dated May 25, 2026

Published: 5/25/2026 | Effective: 6/3/2026 | Type: Legal act

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Uzbekistan registration/licensing update — review for wizard applicability.		
SB Wizard Impact	Review Uzbekistan wizard for updated registration requirements; assess impact on dossier content.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://yuz.uz/ru/news/v-uzbekistane-ustanovlen-poryadok-inspeksionnogo-kontrol...		

Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirements

Published: 6/5/2026 | Effective: | Type: Guidance

Impact Domain	Classification	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Certain unclassified devices may be exempt from 510(k) — review eligibility criteria.		
SB Wizard Impact	Review exemption eligibility logic in FDA 510(k) wizard; update classification/exemption screening questions if affected device types are covered.		
Regulatory Delta	New exemption list expands the set of devices not requiring premarket notification; SB wizard eligibility logic may need updating.		
Affected Wizard/Pathway	FDA 510(k) new registration wizard — eligibility screening		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.fda.gov/media/89238/download		

Guidelines for Regulatory Trust (Reliance) and Recognition Practices in Good Manufacturing Practice (GMP) Inspection for Pharmaceuticals

Published: 5/13/2026 | Effective: 5/13/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Algeria regulatory reliance/recognition guidance — updated procedures for reliance on other regulators.		
SB Wizard Impact	Review Algeria MD wizard reliance pathway; update documentation requirements and eligible reference regulators.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://anpp.dz/fr/guidelines/		

China NMPA Issues Announcement on Medical Device Classification Adjustment Procedures

Published: 6/1/2026 | Effective: 6/1/2026 | Type: Notification

Impact Domain	Classification	Impact Category	Conditional logic or pathway update
Regulated-party Impact	NMPA classification adjustment — device classification codes or categories updated.		
SB Wizard Impact	Review China wizard classification logic; update classification codes/categories if affected devices are covered.		
Regulatory Delta	NMPA classification adjustment announcement — compare classification changes with current wizard lookup tables.		
Affected Wizard/Pathway	China MD/IVD new registration wizard — classification section		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxgtggtg/20260601172053198.html		

Guideline on Minimum Requirements for Inspecting Group III and Group IV Hazardous Substances

Published: 6/10/2026 | Effective: 6/10/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	SAHPRA guidance on specific device categories (MRI, laser, electromedical) under Hazardous Substances Act.		
SB Wizard Impact	Review South Africa wizard for Hazardous Substances Act pathway; update if MRI/laser/electromedical device guidance is not currently reflected.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	South Africa MD registration wizard — Hazardous Substances Act pathways		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.sahpra.org.za/document/guideline-on-minimum-requirements-for-inspect...		

Deviation from Conformity Assessment Procedures

Published: 6/10/2026 | Effective: | Type: Notification

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Hungary notified body and conformity assessment body updates — manufacturers using Hungarian NBs should verify status.		
SB Wizard Impact	Review Hungary wizard for conformity assessment pathway options; update NB list if affected.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://ogyei.gov.hu/a_megfelelosegertekelesi_eljarasoktol_valo_elteres		

Conformity Assessment Bodies

Published: 6/10/2026 | Effective: | Type: Notification

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Hungary notified body and conformity assessment body updates — manufacturers using Hungarian NBs should verify status.		
SB Wizard Impact	Review Hungary wizard for conformity assessment pathway options; update NB list if affected.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://ogyei.gov.hu/megfelelosegertekelo_szervezetek		

Regulation of Medical Devices in Northern Ireland

Published: 6/11/2026 | Effective: 6/11/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Updated MHRA guidance on NI device registration and custom-made device clarifications; changes effective May 28, 2026.		
SB Wizard Impact	Review Northern Ireland wizard pathway; verify NI vs GB routing logic; update custom-made device exception handling.		
Regulatory Delta	MHRA updated NI registration requirements and custom-made clarifications effective May 28, 2026.		
Affected Wizard/Pathway	UK/NI MD registration wizard; custom-made device pathway		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gov.uk/guidance/medical-devices-eu-regulations-for-mdr-and-ivdr#full...		

Labeling Guideline for Digital Medical Devices

Published: 6/10/2026 | Effective: 6/10/2026 | Type: Guidance

Impact Domain	Classification	Impact Category	Wizard content update
Regulated-party Impact	Updated Korea guidance on digital medical devices, SaMD classification, and change control plans.		
SB Wizard Impact	Review Korea SaMD/digital device wizard; update classification criteria, labelling guidance, and change control wizard per updated MFDS guidance.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	Korea SaMD / digital medical device wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.mfds.go.kr/brd/m_1060/view.do?seq=15870&srchFr=&srchTo=&srchWord=&sr...		

Medical Device Manufacturing and Quality Control Standards

Published: 6/12/2026 | Effective: TBD | Type: Draft

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Korea MFDS regulatory update.		
SB Wizard Impact	Review Korea wizard for updated regulatory references.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.mfds.go.kr/brd/m_209/view.do?seq=44254&srchFr=&srchTo=&srchWord=&src...		

GN-02: Guidance Notes for Listing Class II/III/IV General Medical Devices

Published: 6/12/2026 | Effective: 6/12/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	Monitor for applicability.		
SB Wizard Impact	Review Hong Kong Class II/III/IV general MD listing wizard against updated guidance GN-02.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	Hong Kong Class II/III/IV general MD listing wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.mdd.gov.hk/tc/whats-new/mdacs-activities/index-id-2365.html		

GN-06: Guidance Notes for Listing Class B/C/D In Vitro Diagnostic Medical Devices

Published: 6/12/2026 | Effective: 6/12/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	Monitor for applicability.		
SB Wizard Impact	Review Hong Kong Class B/C/D IVD listing wizard against updated guidance GN-06.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	Hong Kong IVD listing wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.mdd.gov.hk/tc/whats-new/mdacs-activities/index-id-2365.html		

ANVISA Expands Support and Improvement Measures to Support the Transition to the New Importation System

Published: 6/12/2026 | Effective: 6/12/2026 | Type: Circular

Impact Domain	Import authorization	Impact Category	Instructions/reference update only
Regulated-party Impact	Updated ANVISA DUIMP importation guidance — importers must follow updated v1.9 procedures.		
SB Wizard Impact	Review Brazil import wizard for updated DUIMP procedures; update instructions and references to guidance version 1.9.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/2026/transicao-para-nov...		

On Amendments to the Resolution of the Cabinet of Ministers of the Kyrgyz Republic “On Approval of the Procedure for Compiling and Criteria for the Exclusion and Inclusion of Medicines and Medical Devices in a Special List of Medicines and Medical Devices Temporarily Permitted for Import and Medical Use Without Registration” dated August 23, 2025 No. 522

Published: 6/8/2026 | Effective: 6/18/2026 | Type: Government's Decree

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Kyrgyzstan registration/licensing update — review for wizard applicability.		
SB Wizard Impact	Review Kyrgyzstan wizard for updated registration requirements; assess impact on dossier content.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://cbd.minjust.gov.kg/7-55651/edition/54132/ru		

China’s NMPA Announces Removal of 10 Medical Device Industry Standards, Including Transcatheter Heart Valve Spec

Published: 6/5/2026 | Effective: 6/5/2026 | Type: Notification

Impact Domain	Product-specific technical evidence	Impact Category	Wizard content update
Regulated-party Impact	NMPA removes obsolete industry standards — affected devices must reference updated standards.		
SB Wizard Impact	Review China wizard standards reference lists; remove retired standards and add replacement standards if applicable.		
Regulatory Delta	10 NMPA medical device industry standards removed — verify current wizard references do not include retired standards.		
Affected Wizard/Pathway	China MD/IVD registration wizard — standards compliance section		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxhybzhgg/20260605170322135.html		

Cofepris has published an update to the Guide to Requirements for the Sanitary Registration Process

Published: 6/17/2026 | Effective: 6/17/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	COFEPRIS updated guide to requirements for sanitary registration of medical devices.		
SB Wizard Impact	Review Mexico MD registration wizard against updated COFEPRIS requirements guide; update checklist and documentation requirements.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.gob.mx/cms/uploads/attachment/file/1084062/GUIA_DE_REQUISITOS_VIA_R_...		

Guideline on Minimum Requirements for Inspecting Group III and Group IV Hazardous Substances

Published: 6/15/2026 | Effective: 6/15/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Wizard content update
Regulated-party Impact	SAHPRA guidance on specific device categories (MRI, laser, electromedical) under Hazardous Substances Act.		
SB Wizard Impact	Review South Africa wizard for Hazardous Substances Act pathway; update if MRI/laser/electromedical device guidance is not currently reflected.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	South Africa MD registration wizard — Hazardous Substances Act pathways		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.sahpra.org.za/document/guideline-on-minimum-requirements-for-inspect...		

Guidance on standardisation for medical devices

Published: 6/17/2026 | Effective: | Type: Guidance

Impact Domain	Product-specific technical evidence	Impact Category	Instructions/reference update only
Regulated-party Impact	Updated EU guidance on standardisation for medical devices — harmonised standards reference updated.		
SB Wizard Impact	Review EU wizard for harmonised standards references; update if specific standards are added or withdrawn.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://health.ec.europa.eu/document/download/59ac4cb0-f187-4ca2-814d-82c42cde54...		

Enforcement Decree of the Medical Device Act

Published: 6/23/2026 | Effective: 7/1/2026 | Type: Enforcement Decree

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Korea Medical Device Act Enforcement Decree updated — regulatory framework changes.		
SB Wizard Impact	Review Korea wizard for enforcement decree changes; update pathway logic and requirements per amended decree.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.law.go.kr/%EB%B2%95%EB%A0%B9/%EC%9D%98%EB%A3%8C%EA%B8%B0%EA%B8%B0%EB...		

New UDI Newsletter

Published: 6/22/2026 | Effective: N/A | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/products/medical-devices/labelling-and-advertising/unique...		

Getting started with UDI

Published: 6/22/2026 | Effective: N/A | Type: Notification

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/products/medical-devices/labelling-and-advertising/unique...		

Complying with the Unique Device Identification timeframes for medical devices

Published: 6/24/2026 | Effective: N/A | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Wizard content update
Regulated-party Impact	Updated TGA UDI requirements/guidance — manufacturers and sponsors must comply with updated UDI labelling, database, and trigger requirements.		
SB Wizard Impact	Review Australia UDI wizard for updated AusUDID submission methods, data elements, labelling/packaging requirements, UDI triggers and timeframes; update instructions and content per updated TGA guidance set.		
Regulatory Delta	Multiple TGA UDI guidance pages updated — check AusUDID access, data elements, grace periods, labelling requirements.		
Affected Wizard/Pathway	Australia UDI registration wizard; AusUDID submission wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.tga.gov.au/resources/guidance/complying-unique-device-identification...		

China's NMPA Issues 2026 Revised Registration Review Guidelines for Medical MRI Systems

Published: 6/23/2026 | Effective: 6/23/2026 | Type: Guidance

Impact Domain	Product-specific technical evidence	Impact Category	Wizard content update
Regulated-party Impact	NMPA technical review guidance update — device-specific registration requirements updated.		
SB Wizard Impact	Review China wizard for product-specific technical sections affected by updated NMPA registration review guidelines.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.cmde.org.cn/xwdt/shpgzgq/gztg/20260623092501160.html		

China's NMPA Releases Technical Review Guidelines for Varicose Vein Closure Adhesive Devices

Published: 6/18/2026 | Effective: 6/18/2026 | Type: Notification

Impact Domain	Product-specific technical evidence	Impact Category	Wizard content update
Regulated-party Impact	NMPA technical review guidance update — device-specific registration requirements updated.		
SB Wizard Impact	Review China wizard for product-specific technical sections affected by updated NMPA registration review guidelines.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.cmde.org.cn/xwdt/shpgzgq/gztg/20260618145109105.html		

China's NMPA Issues Trial Technical Review Guidelines for Tumor Gene Variant Detection Reagents

Published: 6/15/2026 | Effective: 6/15/2026 | Type: Notification

Impact Domain	Product-specific technical evidence	Impact Category	Wizard content update
Regulated-party Impact	NMPA technical review guidance update — device-specific registration requirements updated.		
SB Wizard Impact	Review China wizard for product-specific technical sections affected by updated NMPA registration review guidelines.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.cmde.org.cn/xwdt/shpgzgq/gztg/20260615154311124.html		

Enforcement Decree of the Medical Device Act

Published: 6/23/2026 | Effective: 7/1/2026 | Type: Guidance

Impact Domain	Registration dossier	Impact Category	Conditional logic or pathway update
Regulated-party Impact	Korea Medical Device Act Enforcement Decree updated — regulatory framework changes.		
SB Wizard Impact	Review Korea wizard for enforcement decree changes; update pathway logic and requirements per amended decree.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.law.go.kr/%EB%B2%95%EB%A0%B9/%EC%9D%98%EB%A3%8C%EA%B8%B0%EA%B8%B0%EB...		

Approval and Review Guideline for Digital Medical Device Change Control Plans

Published: 6/26/2026 | Effective: 6/26/2026 | Type: Guidance

Impact Domain	Classification	Impact Category	Wizard content update
Regulated-party Impact	Updated Korea guidance on digital medical devices, SaMD classification, and change control plans.		
SB Wizard Impact	Review Korea SaMD/digital device wizard; update classification criteria, labelling guidance, and change control wizard per updated MFDS guidance.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	Korea SaMD / digital medical device wizard		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
Official Source	https://www.mfds.go.kr/brd/m_1060/view.do?seq=15874&srchFr=&srchTo=&srchWord=&sr...		

Extension of Registration Period for High-Risk Medical Devices and Supplies Manufacturers and Their Products

Published: 6/28/2026 | Effective: 6/28/2026 | Type: Circular

Impact Domain	Registration dossier	Impact Category	Instructions/reference update only
Regulated-party Impact	Oman registration/licensing update — review for wizard applicability.		
SB Wizard Impact	Review Oman wizard for updated registration requirements; assess impact on dossier content.		
Regulatory Delta	No substantive wizard-relevant change identified.		
Affected Wizard/Pathway	N/A		
Recommended Action	Schedule review	Confidence	Low Pending human validation
Official Source	https://www.moh.gov.om/media/zisn2dzq/cirno64-of-2026-regarding-extension-of-reg...		

Updated Clinical Investigation Submission Guidance (IRAS)

Published: 2026-06-01 (est.) | Effective: 2026-06-01 (est.) | Type: Guidance

Impact Domain	Clinical investigation	Impact Category	Wizard content update
Regulated-party Impact	Clinical investigation applications must follow updated MHRA guidance including revised IRAS form integration and updated supporting document requirements.		
SB Wizard Impact	Review UK clinical investigation wizard for IRAS form integration; update supporting document checklist and instructions per updated MHRA guidance.		
Regulatory Delta	Previously: MHRA clinical investigation guidance with prior IRAS version. Now: updated guidance with revised IRAS form and supporting documents. Exact delta requires document comparison.		
Affected Wizard/Pathway	UK Clinical Investigation wizard (if in SB scope)		
Recommended Action	Schedule review	Confidence	Medium Pending human validation
⚠️ Note: MISSING ALERT — identified from UK alert stream; not in spreadsheet.			
Official Source	https://www.gov.uk/guidance/medical-devices-clinical-investigations		

MDCG 2026-5: UDI Assignment Between Manufacturers and Distributors

Published: 2026-04-01 (est.) | Effective: 2026-04-01 (est.) | Type: Guidance

Impact Domain	UDI/device registration	Impact Category	Manual review needed
Regulated-party Impact	MDCG clarifies UDI assignment responsibility between manufacturers and distributors — parties must confirm correct UDI ownership and data submission responsibilities.		
SB Wizard Impact	Review manufacturer/distributor role logic and UDI ownership fields in EU UDI registration wizards; no XSD change confirmed — manual review of manufacturer vs. distributor UDI responsibility logic required.		
Regulatory Delta	Previously: UDI assignment guidance lacked explicit manufacturer/distributor split. Now: MDCG 2026-5 clarifies roles. Does NOT confirm XSD or data model change.		
Affected Wizard/Pathway	EU MDR/IVDR UDI registration wizard — manufacturer/distributor role fields		
Recommended Action	Escalate for manual review	Confidence	Medium Pending human validation
⚠️ Note: MISSING ALERT — MDCG 2026-5; no XSD change inferred from guidance alone.			
Official Source	https://health.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-en...		

Watchlist

15 alerts under active monitoring — no SB action until final publication

Alert ID	Country	Title	Status / Why Watchlisted	Next Review Trigger
China_May 6, 2026, 5:18:12 AM	China	NMPA Seeks Public Comments on Three Medical Device Registrat...	Monitor only — implement only after final publication and regulatory delta review against current wizard.	Finalization of draft/consultation; or further official confirmation required
United Kingdom_May 13, 2026, 11:17:12 AM	United Kingdom	MHRA invites Views on Proposed Changes to Medical Device Reg...	Monitor — implement only after final rule published and delta assessed.	Finalization of draft/consultation; or further official confirmation required
Kazakhstan_May 20, 2026, 9:03:34 AM	Kazakhstan	Resolution of the Government of the Republic of Kazakhstan "...	No SB action until final publication.	Finalization of draft/consultation; or further official confirmation required
Kazakhstan_May 20, 2026, 9:08:10 AM	Kazakhstan	On Amendments to the Order of the Minister of Health of the ...	No SB action until final publication.	Finalization of draft/consultation; or further official confirmation required
China_May 21, 2026, 7:59:08 AM	China	China Seeks Public Comment on Draft Registration Review Guid...	Monitor only — implement only after final publication and regulatory delta review against current wizard.	Finalization of draft/consultation; or further official confirmation required
China_May 21, 2026, 7:57:06 AM	China	China Seeks Public Comment on Draft Registration Review Guid...	Monitor only — implement only after final publication and regulatory delta review against current wizard.	Finalization of draft/consultation; or further official confirmation required
China_May 21, 2026, 7:54:51 AM	China	China Releases Draft Guidance for Public Comment on Three Me...	Monitor only — implement only after final publication and regulatory delta review against current wizard.	Finalization of draft/consultation; or further official confirmation required
Kazakhstan_May 25, 2026, 9:28:21 AM	Kazakhstan	On amendments and additions to the joint order of the Minist...	No SB action until final publication.	Finalization of draft/consultation; or further official confirmation required
United States_Jun 3, 2026, 5:21:20 AM	United States	Drug and Device Manufacturer Communications With Payors, For...	No SB action until final guidance published; watchlist for potential labeling/IFU communication requirements.	Finalization of draft/consultation; or further official confirmation required
China_Jun 11, 2026, 2:37:51 AM	China	China NMPA Seeks Public Input on Four Draft Medical Device R...	Monitor only — implement only after final publication and regulatory delta review against current wizard.	Finalization of draft/consultation; or further official confirmation required
China_Jun 11, 2026, 2:46:33 AM	China	China NMPA Opens Public Consultation on Draft Registration R...	Monitor only — implement only after final publication and regulatory delta review against current wizard.	Finalization of draft/consultation; or further official confirmation required
Kazakhstan_Jun 11, 2026, 11:09:46 AM	Kazakhstan	On amendments to the order of the Minister of Health of the ...	No SB action until final publication.	Finalization of draft/consultation; or further official confirmation required

Sweden_Jun 22, 2026, 9:55:06 AM	Sweden	The Swedish Medicines Agency will be responsible for AI syst...	Monitor for regulatory framework finalization; no SB action until concrete requirements published.	Finalization of draft/consultation; or further official confirmation required
Kyrgyzstan_Jun 25, 2026, 9:35:32 AM	Kyrgyzstan	Government's Decree	No SB action until final publication.	Finalization of draft/consultation; or further official confirmation required
China_Jun 26, 2026, 3:47:34 AM	China	China's NMPA Invites Industry Participation in Drafting Regi...	Monitor only — implement only after final publication and regulatory delta review against current wizard.	Finalization of draft/consultation; or further official confirmation required

Rule: Draft guidance, consultations, and unverified revisions must NOT enter the wizard update queue. Implement only after: (1) final rule published, (2) regulatory delta confirmed vs. previous version, (3) wizard baseline compared, (4) SB owner approves.

No SB Action Register

95 alerts assessed as requiring no Submission Builder wizard action

Alert ID	Country	Title	Reason Excluded from SB Scope
Mexico_May 5, 2026, 7:00:26 PM	Mexico	Cofepris has published the "Agreement establishing measures to streaml...	COFEPRIS operational update — email notifications, reliance platform, or fee/inv...
Mexico_May 5, 2026, 7:01:45 PM	Mexico	Cofepris has published the "Agreement Updating the Methods for Submitt...	COFEPRIS regulatory update.
Iraq_May 6, 2026, 1:09:47 PM	Iraq	Circular to Scientific Offices and Companies	Iraq regulatory update — operational or informational in nature.
Chile_May 7, 2026, 3:16:35 PM	Chile	Exempt Resolution No. 2.050/2026 approves the "Guidelines for Clinical...	Chile regulatory update — operational or informational in nature.
Chile_May 7, 2026, 3:17:47 PM	Chile	Exempt Resolution No. E1.199/2026 approves the services and fees of th...	Chile fee update — update wizard fee references if displayed.
Chile_May 7, 2026, 3:18:38 PM	Chile	ISP Announces New Certification Program for Domestic and Innovative Me...	Chile regulatory update — operational or informational in nature.
Spain_May 7, 2026, 4:10:10 AM	Spain	The AEMPS Updates the Information on the Medical Device Surveillance S...	Spain regulatory update — operational or informational in nature.
Denmark_May 7, 2026, 5:18:45 AM	Denmark	Medical Devices with Incorporated Drug	Denmark regulatory notification.
Switzerland_May 7, 2026, 6:31:53 AM	Switzerland	Manufacturer Incident Report Guideline	Updated templates for periodic safety reporting and trend/incident reports to Sw...
Pakistan_May 13, 2026, 4:03:24 AM	Pakistan	Implementation of Online System for Submission and Processing of Appel...	Pakistan regulatory update — operational or informational in nature.
Guyana_May 13, 2026, 3:41:10 PM	Guyana	The Guyana Electronic Single Window (GESW) for permits, licenses, and ...	Guyana regulatory update — operational or informational in nature.
Egypt_May 14, 2026, 7:53:14 AM	Egypt	Regulatory Guideline on Requirements for Unique Device Identification ...	Egypt regulatory update — operational or informational in nature.
Nicaragua_May 14, 2026, 1:38:13 PM	Nicaragua	New Importation/Exportation Form	Nicaragua regulatory update — operational or informational in nature.
Argentina_May 14, 2026, 3:00:40 PM	Argentina	ANMAT promotes Regional Regulatory Cooperation and Regulatory updates ...	Argentina regulatory update — operational or informational in nature.
Paraguay_May 14, 2026, 3:04:21 PM	Paraguay	DINAVISA has published Resolution No. 189/2026	Paraguay regulatory update — operational or informational in nature.
Finland_May 12, 2026, 6:43:00 AM	Finland	Medical Device Manufacturers must report Serious Incidents using a New...	Fimea requires serious incident reports via new form — post-market surveillance ...
Bahrain_May 15, 2026, 12:43:50 AM	Bahrain	Launch of TATABU Medical Devices & Supplies Traceability System	Bahrain regulatory update — operational or informational in nature.

Peru_May 18, 2026, 4:13:52 PM	Peru	DIGEMID - Announcement No. 006/2026	Peru regulatory update — operational or informational in nature.
Vietnam_May 18, 2026, 5:44:01 AM	Vietnam	Notice on Domain Change for the Online Public Service Portal of Vietna...	Vietnam regulatory update — operational or informational in nature.
Ireland_May 15, 2026, 5:12:06 AM	Ireland	Guide to Pre-submission Scientific and Regulatory Advice for GXP Activ...	Ireland regulatory update — operational or informational in nature.
Finland_May 18, 2026, 6:04:12 AM	Finland	The NIS2 Operator Notification is made in Fimea's Electronic Services.	NIS2 cybersecurity operator notification requirement — IT/operational compliance...
Algeria_May 20, 2026, 5:06:32 AM	Algeria	Note No. 44 to Pharmaceutical Establishment Requirement for Tax Cleara...	Algeria regulatory notice — tax clearance or operational requirement.
Argentina_May 19, 2026, 6:55:05 PM	Argentina	ANMAT updates fees and reduces costs for 75% of importers of medicines...	Argentina fee update — update wizard fee references if displayed.
Turkey_May 20, 2026, 11:25:21 AM	Turkey	Attention of Clinical Trial Parties	SUSAR XML reporting (ICH E2B R3) mandatory from July 1 — clinical safety reporti...
Turkey_May 21, 2026, 10:24:53 AM	Turkey	Attention of Clinical Trial Parties	Turkey clinical trial notification/guidance update.
Mexico_May 21, 2026, 3:51:57 PM	Mexico	Guidelines for promoting National Investment in the production of Medi...	COFEPRIS operational update — email notifications, reliance platform, or fee/inv...
Italy_May 21, 2026, 4:30:53 AM	Italy	Injectable Fillers: Clarifications on Distribution and Sales Methods	Italy regulatory update — operational or informational in nature.
Peru_May 22, 2026, 1:31:34 PM	Peru	DIGEMID has published Ministerial Resolution No. 193-2026/MINSA	Peru regulatory update — operational or informational in nature.
Egypt_May 24, 2026, 11:28:21 AM	Egypt	Progress Follow-Up Report Template Clinical Trial of an Investigationa...	Egypt regulatory update — operational or informational in nature.
Algeria_May 25, 2026, 4:39:11 AM	Algeria	Note No. 45 to Pharmaceutical Establishments on Submission of Tax Clea...	Algeria regulatory notice — tax clearance or operational requirement.
Ecuador_May 25, 2026, 5:03:52 PM	Ecuador	Organic Law for Strengthening Cibersecurity	Ecuador regulatory update — operational or informational in nature.
Kazakhstan_May 22, 2026, 11:43:51 AM	Kazakhstan	Order of the Minister of Health of the Republic of Kazakhstan from May...	Kazakhstan regulatory update — operational or informational in nature.
Chile_May 26, 2026, 1:41:55 PM	Chile	ISP and CORFO Launch Strategic Project to Strengthen Medical Device Re...	Chile regulatory update — operational or informational in nature.
Sweden_May 26, 2026, 4:21:31 AM	Sweden	Regulations (HSLF-FS 2026:11) amending the Medical Products Agency's r...	Sweden MPA regulatory update or survey.
Switzerland_May 27, 2026, 6:51:23 AM	Switzerland	Template Trend Report	Updated templates for periodic safety reporting and trend/incident reports to Sw...
Switzerland_May 27, 2026, 6:57:15 AM	Switzerland	Template PSR Report	Updated templates for periodic safety reporting and trend/incident reports to Sw...
Sweden_May 27, 2026, 8:48:56 AM	Sweden	The Swedish Medicines Agency Strengthens Preparedness – Surveys the Me...	Sweden MPA regulatory update or survey.

South Africa_May 28, 2026, 8:49:06 AM	South Africa	Guideline on How to Respond to a GMP, GWP, GCP or GVP Inspection Repor...	SAHPRA guidance on responding to GMP/GWP/GCP/GVP inspection reports or minimum i...
India_May 28, 2026, 4:37:20 AM	India	Regulatory Guidelines for Sampling of Drugs, Cosmetics & Medical Devic...	India CDSCO regulatory circular on sampling of drugs, cosmetics and medical devi...
Denmark_May 28, 2026, 9:33:55 AM	Denmark	Registration Fee	Denmark annual fee or registration fee — manufacturer compliance obligation.
Denmark_May 28, 2026, 9:37:25 AM	Denmark	Distributor and Specialist Store Registration	Denmark DKMA information on EUDAMED mandatory registration and economic operator...
Colombia_May 29, 2026, 2:03:58 PM	Colombia	Invima Hosts a Conference on Healthcare Technologies from a Regulatory...	Colombia regulatory update — operational or informational in nature.
Tanzania_Jun 1, 2026, 4:04:02 AM	Tanzania	Explanation of the Challenges of the New Joint Load Relief System (TAN...	Tanzania regulatory update — operational or informational in nature.
Cameroon_Jun 1, 2026, 4:52:19 AM	Cameroon	Implementation of a combined Individual Case Safety Report (ICSR)/line...	Cameroon regulatory update — operational or informational in nature.
Iraq_Jun 1, 2026, 6:42:00 AM	Iraq	Announcement from the Pharmacy Department, Private Sector Division, to...	Iraq regulatory update — operational or informational in nature.
Singapore_May 29, 2026, 4:36:56 AM	Singapore	How Medical Devices are Regulated by HSA and their Safe Use	HSA regulatory information — general awareness.
United States_May 29, 2026, 5:12:01 AM	United States	Content of Human Factors Information in Medical Device Marketing Submi...	Manufacturer compliance alert — review for applicable operations.
Slovenia_May 29, 2026, 6:07:36 AM	Slovenia	Q&A Education May 13, 2026: Obligations of Distributors and Importers	Slovenia regulatory update — operational or informational in nature.
Denmark_Jun 1, 2026, 5:10:11 AM	Denmark	Annual Fee	Denmark annual fee or registration fee — manufacturer compliance obligation.
Argentina_Jun 2, 2026, 3:02:56 PM	Argentina	Update on fees for ANMAT procedures	Argentina fee update — update wizard fee references if displayed.
Syria_Jun 3, 2026, 6:09:04 AM	Syria	Regulatory Decision 8/T	Syria regulatory update — operational or informational in nature.
Oman_Jun 3, 2026, 6:38:07 AM	Oman	Requirements for Approval of Optical Companies Applying for Medical De...	Oman regulatory update — operational or informational in nature.
Iraq_Jun 3, 2026, 9:39:07 AM	Iraq	Circular No. 9/2/1163 To All Scientific Offices and National Factories	Iraq regulatory update — operational or informational in nature.
Uzbekistan_Jun 2, 2026, 12:43:36 PM	Uzbekistan	New legislative changes will come into force in Uzbekistan on June 1	Uzbekistan regulatory update — operational or informational in nature.
Uzbekistan_Jun 2, 2026, 12:48:35 PM	Uzbekistan	On measures to provide additional support to the private sector in the...	Uzbekistan regulatory update — operational or informational in nature.
Germany_Jun 5, 2026, 4:02:06 AM	Germany	Instructions for those Required to Report Address Ads	Germany BfArM address notification or self-declaration requirement.
Australia_Jun 8, 2026, 7:02:02 AM	Australia	Annual charge waiver guidelines - How to apply for an annual charge wa...	TGA update — operational or post-market in nature.

Srilanka_Jun 8, 2026, 7:07:22 AM	Srilanka	Reissuance of Sample Import License (SIL)-Medical Devices	Srilanka regulatory update — operational or informational in nature.
Srilanka_Jun 8, 2026, 7:09:35 AM	Srilanka	Checklist for Document Accepting of Consolidated new Medical Device ap...	Srilanka regulatory update — operational or informational in nature.
Algeria_Jun 8, 2026, 10:56:20 AM	Algeria	Regulatory Inspections Guideline	Algeria regulatory inspection guideline update.
Bolivia_Jun 9, 2026, 1:29:07 PM	Bolivia	Cyber Attack at AGEMED Systems	Bolivia regulatory update — operational or informational in nature.
Nicaragua_Jun 9, 2026, 1:34:15 PM	Nicaragua	Public Consultation 175 - (NTON) 24001	Nicaragua regulatory update — operational or informational in nature.
Lebanon_Jun 9, 2026, 2:42:46 PM	Lebanon	Circular No. 22 Regarding the Entry of Import Invoices for Non-Implant...	Lebanon circulars on import invoice requirements for medical devices (non-implan...
Lebanon_Jun 9, 2026, 2:47:58 PM	Lebanon	Circular No. 23 Regarding FDA-Approved Implantable Medical Devices	Lebanon circulars on import invoice requirements for medical devices (non-implan...
Qatar_Jun 10, 2026, 9:54:59 AM	Qatar	Customs Union Authority Launches “Taysir” System to Address Trade Obst...	Qatar regulatory update — operational or informational in nature.
Botswana_Jun 10, 2026, 10:33:33 AM	Botswana	Notice of Implementation of a Combined Screening and Evaluation Proces...	Botswana regulatory update — operational or informational in nature.
Germany_Jun 10, 2026, 3:48:38 AM	Germany	Self-declaration Regarding the Implementation of the Requirements for ...	Germany BfArM address notification or self-declaration requirement.
Latvia_Jun 10, 2026, 4:18:12 AM	Latvia	The Government Supports the Consolidation of Supervision of the Pharma...	Latvia regulatory update — operational or informational in nature.
Singapore_Jun 11, 2026, 4:32:35 AM	Singapore	Mean Applicant Screening Response Time Audiences	HSA regulatory information — general awareness.
South Africa_Jun 11, 2026, 10:00:11 AM	South Africa	Application for Authority for the Temporary Use, Possession and Transp...	SAHPRA update — operational in nature.
Algeria_Jun 11, 2026, 12:02:58 PM	Algeria	Note to Pharmaceutical Institutions	Algeria regulatory notice — tax clearance or operational requirement.
Lithuania_Jun 11, 2026, 4:28:41 AM	Lithuania	Information Regarding a Cyber Incident	Lithuania regulatory update — operational or informational in nature.
Lithuania_Jun 11, 2026, 4:33:25 AM	Lithuania	VASPVt Informs About the Controlled Cyber Incident in the Information ...	Lithuania regulatory update — operational or informational in nature.
Norway_Jun 15, 2026, 5:02:09 AM	Norway	Medical Device Supervision Shows Challenges with Cosmetic Clinics and ...	Norway regulatory update — operational or informational in nature.
United States_Jun 16, 2026, 11:30:56 AM	United States	TESTING ISSUES	Test/internal entry — not a regulatory alert.
Australia_Jun 18, 2026, 9:31:14 AM	Australia	TGA Releases New Guidance on Advertising Restrictions for Prescription...	TGA update — operational or post-market in nature.
Peru_Jun 18, 2026, 4:37:01 PM	Peru	Announcement No. 008/2026 - Webinar on the Medical Device Risk Managem...	Peru regulatory update — operational or informational in nature.

Costa Rica_Jun 19, 2026, 2:26:44 PM	Costa Rica	Digital systems will be temporarily out of service	Costa Rica regulatory update — operational or informational in nature.
Belarus_Jun 19, 2026, 4:12:34 AM	Belarus	Transfer of Medical Device Regulatory Functions in Belarus	Belarus regulatory update — operational or informational in nature.
Rwanda_Jun 22, 2026, 8:37:42 AM	Rwanda	Regulations Governing Good Manufacturing Practices of Medical Products	Rwanda regulatory update — operational or informational in nature.
Bolivia_Jun 22, 2026, 3:05:41 PM	Bolivia	AGEMED/CE/021/2026	Bolivia regulatory update — operational or informational in nature.
Bolivia_Jun 22, 2026, 3:18:01 PM	Bolivia	MSyD/AGEMED/CR/19/2026	Bolivia regulatory update — operational or informational in nature.
Botswana_Jun 22, 2026, 6:47:11 PM	Botswana	BOMRA Medical Devices, including IVDs, Regulatory Update: Medical Devi...	Botswana regulatory update — operational or informational in nature.
Switzerland_Jun 22, 2026, 4:58:30 AM	Switzerland	Amendment to the Swissmedic Fee Ordinance as of July 1, 2026	Swissmedic fee ordinance updated July 1, 2026 — per-UDI-DI fees apply in Swissda...
Bahrain_Jun 23, 2026, 4:06:24 PM	Bahrain	Updated Fee Schedules of Services and Requests for Medical Devices and...	Bahrain fee update — update wizard fee references if displayed.
Mexico_Jun 23, 2026, 4:29:40 PM	Mexico	Update on the Reliance Regulatory Fast Track Platform	COFEPRIS operational update — email notifications, reliance platform, or fee/inv...
Australia_Jun 24, 2026, 6:10:20 AM	Australia	Unique Device Identification Consent to Supply process	TGA update — operational or post-market in nature.
Brazil_Jun 24, 2026, 1:47:47 PM	Brazil	ANVISA Opens Public Call for Proposals to Improve Technovigilance Rule...	ANVISA operational update — monitoring or circular.
Denmark_Jun 24, 2026, 4:45:59 AM	Denmark	Fees for Clinical Trials of Medical Devices	Denmark annual fee or registration fee — manufacturer compliance obligation.
Kazakhstan_Jun 25, 2026, 2:07:51 PM	Kazakhstan	Law of Kazakhstan On Amendments and Supplements to Certain Legislativ...	Kazakhstan regulatory update — operational or informational in nature.
India_Jun 26, 2026, 4:08:23 AM	India	Sale of In-Vitro Fertilization Media, Reagents, and Related Consumable...	India CDSCO regulatory circular on sampling of drugs, cosmetics and medical devi...
Bolivia_Jun 26, 2026, 12:30:37 PM	Bolivia	CIRCULAR-22-2026	Bolivia regulatory update — operational or informational in nature.
Brazil_Jun 26, 2026, 12:34:24 PM	Brazil	TECHNICAL NOTE Nº 41/2026/SEI/GQUIP/GGTPS/DIRE3/ANVISA	ANVISA operational update — monitoring or circular.
Kuwait_Jun 26, 2026, 7:30:46 PM	Kuwait	Electronic Invoice Release Platform Companies` User Manual	Kuwait regulatory update — operational or informational in nature.
Kyrgyzstan_Jun 28, 2026, 1:21:50 AM	Kyrgyzstan	On Amendments to the Resolution of the Government of the Kyrgyz Republ...	Kyrgyzstan regulatory update — operational or informational in nature.

Full Alert Annex

All 211 alerts assessed (207 from tracker + 4 missing alerts added) | Assessment date: July 29, 2026 | Validation: Pending human validation

Alert ID	Country	Published	Effective	Type	Title	SB Priority	Impact Domain
Malaysia_May 4, 2026, 4:14:21 AM	Malaysia	5/1/2026	5/1/2026	Notification	Joint Announcement by Medical Device Authority (MDA) Malaysi...	P2	Registration dossier
Turkey_May 5, 2026, 11:02:29 AM	Turkey	5/4/2026	5/4/2026	Announcement	Mandatory Use of the EUDAMED Database System (Law No. 2026/K...	P1	UDI/device registration
Mexico_May 5, 2026, 7:00:26 PM	Mexico	5/4/2026	5/15/2026	Agreement	Cofepris has published the "Agreement establishing measures ...	No SB action	Fees and admin
Mexico_May 5, 2026, 7:01:45 PM	Mexico	5/4/2026	5/5/2026	Agreement	Cofepris has published the "Agreement Updating the Methods f...	No SB action	Registration dossier
Iraq_May 6, 2026, 1:09:47 PM	Iraq	5/6/2026	5/6/2026	Circular	Circular to Scientific Offices and Companies	No SB action	Registration dossier
China_May 6, 2026, 5:18:12 AM	China	5/6/2026	5/6/2026	Draft for Comment	NMPA Seeks Public Comments on Three Medical Device Registrat...	Watchlist	Product-specific technical evidence
Australia_May 6, 2026, 5:47:00 AM	Australia	5/4/2026	N/A	Guidance	Accessing and using the AusUDID	P2	UDI/device registration
Australia_May 6, 2026, 5:48:53 AM	Australia	5/4/2026	N/A	Guidance	AusUDID submission methods	P2	UDI/device registration
Australia_May 6, 2026, 5:50:42 AM	Australia	5/4/2026	N/A	Guidance	Accessing the AusUDID	P2	UDI/device registration
Australia_May 6, 2026, 5:52:45 AM	Australia	5/4/2026	N/A	Guidance	AusUDID data elements	P2	UDI/device registration
Saudi Arabia_May 7, 2026, 8:01:04 AM	Saudi Arabia	5/5/2026	5/5/2026	Guidance	Guidance on Bundling Criteria for Medical Devices within a S...	P2	Grouping
Chile_May 7, 2026, 3:16:35 PM	Chile	5/7/2026	5/7/2026	Resolution	Exempt Resolution No. 2.050/2026 approves the "Guidelines fo...	No SB action	Registration dossier
Chile_May 7, 2026, 3:17:47 PM	Chile	5/7/2026	5/7/2026	Resolution	Exempt Resolution No. E1.199/2026 approves the services and ...	No SB action	Fees and admin
Chile_May 7, 2026, 3:18:38 PM	Chile	5/6/2026	5/6/2026	Announcement	ISP Announces New Certification Program for Domestic and Inn...	No SB action	Registration dossier
Spain_May 7, 2026, 4:10:10 AM	Spain	5/4/2026		Notification	The AEMPS Updates the Information on the Medical Device Surv...	No SB action	Registration dossier
United States_May 7, 2026, 4:46:00 AM	United States	5/6/2026	5/7/2026	Guidance	Patient-Matched Guides for Orthopedic Implants	P2	Product-specific technical evidence
European Union_May 7,	European Union	5/5/2026	5/4/2026	Guidance	Implementing Regulation (EU) 2026/977 – Uniform Requirements...	P1	Registration dossier

2026, 4:49:31 AM							
Denmark_May 7, 2026, 5:18:45 AM	Denmark	5/5/2026		Notification	Medical Devices with Incorporated Drug	No SB action	Registration dossier
Switzerland_May 7, 2026, 6:31:53 AM	Switzerland	5/1/2026	5/1/2026	Guidance	Manufacturer Incident Report Guideline	No SB action	Post-market/vigilance
Switzerland_May 7, 2026, 6:35:51 AM	Switzerland	5/1/2026	5/1/2026	Guidance	Information Sheet Combined Studies	P2	Clinical investigation
Saudi Arabia_May 8, 2026, 10:49:12 AM	Saudi Arabia	5/5/2026	5/5/2026	Forms	SFDA Medical Devices Forms Updates	P1	Registration dossier
Turkey_May 8, 2026, 11:31:36 AM	Turkey	5/7/2026	Not Announced	Announcement	TCOKKA - Publication of Implementing Regulation (EU) 2026/97...	P2	Registration dossier
Australia_May 11, 2026, 12:23:40 PM	Australia	5/11/2026	N/A	Guidance	Using assessments from comparable overseas regulators for me...	P2	Registration dossier
Australia_May 11, 2026, 12:24:58 PM	Australia	5/11/2026	N/A	Guidance	Use of market authorisation evidence from comparable oversea...	P2	UDI/device registration
Switzerland_May 11, 2026, 4:55:35 AM	Switzerland	5/10/2026	5/10/2026	Guidance	Swissdamed User Manual Actors	P1	Registration dossier
Algeria_May 12, 2026, 6:19:06 PM	Algeria	5/10/2026	5/10/2026	Notice	Note No. 41 to Pharmaceutical Establishment and Economic Ope...	P2	Classification
Algeria_May 12, 2026, 6:26:49 PM	Algeria	5/11/2026	5/11/2026	Notice	Note No. 42 to Pharmaceutical Establishment Relating to Requ...	P2	Classification
Pakistan_May 13, 2026, 4:03:24 AM	Pakistan	5/10/2026	5/15/2026	Announcement	Implementation of Online System for Submission and Processin...	No SB action	Registration dossier
Hong Kong_May 13, 2026, 4:21:53 AM	Hong Kong	5/13/2026	5/13/2026	Guidance	GN-00: Definitions and Abbreviations for the Medical Device ...	P2	Registration dossier
Guyana_May 13, 2026, 3:41:10 PM	Guyana	5/11/2026	5/11/2026	Announcement	The Guyana Electronic Single Window (GESW) for permits, lice...	No SB action	Registration dossier
Egypt_May 14, 2026, 7:53:14 AM	Egypt	5/14/2026	5/14/2026	Guideline	Regulatory Guideline on Requirements for Unique Device Ident...	No SB action	Registration dossier
Turkey_May 14, 2026, 7:57:58 AM	Turkey	5/13/2026	5/13/2026	Guidance	Guidelines for Registration Processes of Medical Devices in ...	P2	Registration dossier
Nicaragua_May 14, 2026, 1:38:13 PM	Nicaragua	5/13/2026	5/13/2026	Regulation	New Importation/Exportation Form	No SB action	Registration dossier
Argentina_May 14, 2026, 3:00:40 PM	Argentina	5/13/2026	5/4/2026	News	ANMAT promotes Regional Regulatory Cooperation and Regulator...	No SB action	Registration dossier
Paraguay_May 14, 2026, 3:04:21 PM	Paraguay	5/13/2026	5/13/2026	Resolution	DINAVISA has published Resolution No. 189/2026	No SB action	Registration dossier
United Kingdom_May 13, 2026, 11:17:12 AM	United Kingdom	5/11/2026		Notification	MHRA invites Views on Proposed Changes to Medical Device Reg...	Watchlist	Registration dossier
United Kingdom_May 14,	United Kingdom	5/13/2026	5/13/2026	Guidance	Medical Devices: Conformity Assessment and the UKCA Mark	P2	Registration dossier

2026, 4:39:17 AM							
Finland_May 12, 2026, 6:43:00 AM	Finland	5/11/2026		Notification	Medical Device Manufacturers must report Serious Incidents u...	No SB action	Post-market/vigilance
Bahrain_May 15, 2026, 12:43:50 AM	Bahrain	5/13/2026	5/13/2026	Circular	Launch of TATABU Medical Devices & Supplies Traceability Sys...	No SB action	Registration dossier
Australia_May 13, 2026, 12:17:04 PM	Australia	5/12/2026	N/A	Guidance	Preparing for an application audit for in-vitro diagnostic m...	P2	UDI/device registration
Malaysia_May 15, 2026, 4:32:33 AM	Malaysia	5/15/2026	5/15/2026	Guidance	Requirements for Labelling of Medical Devices	P1	Labeling/IFU
Malaysia_May 15, 2026, 4:36:56 AM	Malaysia	5/15/2026	5/15/2026	Guidance	Change Management for Registered Medical Devices	P1	Variation/change notification
Ecuador_May 18, 2026, 4:12:44 PM	Ecuador	5/18/2026	1/28/2027	Resolution	ARCSA has published Resolution ARCSA-DE-2026-003-DASP - Tech...	P2	Registration dossier
Peru_May 18, 2026, 4:13:52 PM	Peru	5/15/2026	5/26/2026	Announcement	DIGEMID - Announcement No. 006/2026	No SB action	Registration dossier
Nicaragua_May 18, 2026, 4:24:26 PM	Nicaragua	5/15/2026	5/15/2026	Guidance	User Guide for Requesting the Issuance of a Registration Cer...	P2	Registration dossier
Nicaragua_May 18, 2026, 4:29:51 PM	Nicaragua	5/15/2026	5/15/2026	Guidance	New Official Request Form for Health Registration Certificat...	P2	Registration dossier
Vietnam_May 18, 2026, 5:44:01 AM	Vietnam	5/15/2026	10/1/2026	Notification	Notice on Domain Change for the Online Public Service Portal...	No SB action	Registration dossier
China_May 18, 2026, 6:29:18 AM	China	5/8/2026	5/8/2026	Guidance	China NMPA Issues Guidance on Registration Review for Percut...	P2	Product-specific technical evidence
Ireland_May 15, 2026, 5:12:06 AM	Ireland	5/13/2026	5/13/2026	Guidance	Guide to Pre-submission Scientific and Regulatory Advice for...	No SB action	Registration dossier
United Kingdom_May 18, 2026, 5:31:16 AM	United Kingdom	5/14/2026	5/14/2026	Guidance	Clinical Investigations for Medical Devices	P2	Clinical investigation
Finland_May 18, 2026, 6:04:12 AM	Finland	5/18/2026		Notification	The NIS2 Operator Notification is made in Fimea's Electronic...	No SB action	QMS/GMP evidence
Serbia_May 19, 2026, 4:54:53 AM	Serbia	5/15/2026	5/15/2026	Guidance	New Conditions and Methods of Recognition of Foreign Documen...	P1	Registration dossier
Serbia_May 19, 2026, 5:10:20 AM	Serbia	5/15/2026	5/15/2026	Guidance	New Conditions and Methods of Recognition of Foreign Certifi...	P1	Registration dossier
Serbia_May 19, 2026, 5:12:59 AM	Serbia	5/15/2026	5/15/2026	Guidance	New Conditions and Methods of Recognition of Foreign Documen...	P1	Registration dossier
Serbia_May 19, 2026, 5:15:08 AM	Serbia	5/15/2026	5/15/2026	Guidance	New Conditions and Methods of Recognition of Foreign Certifi...	P1	Registration dossier
Serbia_May 19, 2026, 5:17:50 AM	Serbia	5/15/2026	5/15/2026	Guidance	Instructions for Submitting a Request for Amendment/Addition...	P1	Registration dossier
Czech Republic_May 19, 2026, 6:05:26 AM	Czech Republic	5/18/2026	5/18/2026	Notification	Application for Authorization to place a Medical Device on t...	P2	Registration dossier

Algeria_May 20, 2026, 5:06:32 AM	Algeria	5/19/2026	5/19/2026	Notice	Note No. 44 to Pharmaceutical Establishment Requirement for ...	No SB action	Fees and admin
Argentina_May 19, 2026, 6:55:05 PM	Argentina	5/19/2026	5/19/2026	Announcement	ANMAT updates fees and reduces costs for 75% of importers of...	No SB action	Fees and admin
Mexico_May 19, 2026, 6:56:59 PM	Mexico	5/19/2026	5/19/2027	Standard	Cofepris has published Mexican Official Standard NOM-137-SSA...	P1	Labeling/IFU
Turkey_May 20, 2026, 11:25:21 AM	Turkey	5/20/2026	7/1/2026	Notification	Attention of Clinical Trial Parties	No SB action	Post-market/vigilance
Brazil_May 20, 2026, 12:53:51 PM	Brazil	5/19/2026	5/19/2026	Circular	ANVISA Launches DUIMP Queue Dashboard and Issues Guidance on...	P2	Import authorization
Kazakhstan_May 20, 2026, 9:03:34 AM	Kazakhstan	5/19/2026	6/4/2026	Draft	Resolution of the Government of the Republic of Kazakhstan "...	Watchlist	Fees and admin
Kazakhstan_May 20, 2026, 9:08:10 AM	Kazakhstan	5/19/2026	6/4/2026	Draft	On Amendments to the Order of the Minister of Health of the ...	Watchlist	Fees and admin
Turkey_May 21, 2026, 10:24:53 AM	Turkey	5/20/2026	5/15/2026	Guidance	Attention of Clinical Trial Parties	No SB action	Clinical investigation
China_May 21, 2026, 7:59:08 AM	China	5/12/2026	5/12/2026	Draft for Comment	China Seeks Public Comment on Draft Registration Review Guid...	Watchlist	Product-specific technical evidence
China_May 21, 2026, 7:57:06 AM	China	5/11/2026	5/11/2026	Draft for Comment	China Seeks Public Comment on Draft Registration Review Guid...	Watchlist	Product-specific technical evidence
China_May 21, 2026, 7:54:51 AM	China	5/6/2026	5/6/2026	Draft for Comment	China Releases Draft Guidance for Public Comment on Three Me...	Watchlist	Product-specific technical evidence
Mexico_May 21, 2026, 3:51:57 PM	Mexico	5/21/2026	5/22/2026	Guidelines	Guidelines for promoting National Investment in the producti...	No SB action	Fees and admin
Italy_May 21, 2026, 4:30:53 AM	Italy	5/20/2026		Notification	Injectable Fillers: Clarifications on Distribution and Sales...	No SB action	Registration dossier
Brazil_May 22, 2026, 12:16:27 PM	Brazil	5/21/2026	5/21/2026	Circular	Importation No. 048/2026	P2	Import authorization
Peru_May 22, 2026, 1:31:34 PM	Peru	5/21/2026	5/21/2026	Resolution	DIGEMID has published Ministerial Resolution No. 193-2026/MI...	No SB action	Registration dossier
Egypt_May 24, 2026, 11:28:21 AM	Egypt	5/24/2026	5/24/2026	Regulation	Progress Follow-Up Report Template Clinical Trial of an Inve...	No SB action	Registration dossier
Algeria_May 25, 2026, 4:39:11 AM	Algeria	5/24/2026	5/24/2026	Notice	Note No. 45 to Pharmaceutical Establishments on Submission o...	No SB action	Fees and admin
Ecuador_May 25, 2026, 5:03:52 PM	Ecuador	5/22/2026	5/22/2026	Regulation	Organic Law for Strengthening Cibersecurity	No SB action	Registration dossier
Kazakhstan_May 22, 2026, 11:43:51 AM	Kazakhstan	5/19/2026	5/29/2026	MOH Order	Order of the Minister of Health of the Republic of Kazakhsta...	No SB action	Registration dossier
Australia_May 22, 2026, 12:23:25 PM	Australia	5/22/2026	N/A	guidance	Complying with the Unique Device Identification timeframes f...	P2	UDI/device registration
Australia_May 22, 2026, 12:24:15 PM	Australia	5/12/2026	N/A	Notification	Preparing for an application audit for in-vitro diagnostic m...	P2	UDI/device registration

Kazakhstan_May 25, 2026, 9:28:21 AM	Kazakhstan	5/22/2026	5/27/2026	Draft	On amendments and additions to the joint order of the Minist...	Watchlist	Fees and admini...
Chile_May 26, 2026, 1:41:55 PM	Chile	5/25/2026	12/5/2025	News	ISP and CORFO Launch Strategic Project to Strengthen Medical...	No SB action	Registration dossier
Czech Republic_May 25, 2026, 5:09:10 AM	Czech Republic	5/18/2026	5/28/2026	Notification	Methodological Instructions for Submitting an Application fo...	P2	Registration dossier
Sweden_May 26, 2026, 4:21:31 AM	Sweden	5/25/2026	5/28/2026	Guidance	Regulations (HSLF-FS 2026:11) amending the Medical Products ...	No SB action	Registration dossier
Portugal_May 26, 2026, 4:31:54 AM	Portugal	5/20/2026	5/28/2026	Circular	Operationalization of EUDAMED on May 28, 2026	P1	UDI/device registration
Korea_May 26, 2026, 1:42:14 PM	Korea	5/26/2026	5/26/2026	Guidance for officials	Approval and Review Procedures for New Technology Medical De...	P2	Registration dossier
Switzerland_May 27, 2026, 6:51:23 AM	Switzerland	5/26/2026	5/26/2026	Notification	Template Trend Report	No SB action	Post-market/vigilance
Switzerland_May 27, 2026, 6:57:15 AM	Switzerland	5/26/2026	5/26/2026	Notification	Template PSR Report	No SB action	Post-market/vigilance
Sweden_May 27, 2026, 8:48:56 AM	Sweden	5/26/2026	Notification	Notification	The Swedish Medicines Agency Strengthens Preparedness – Surv...	No SB action	Registration dossier
Sweden_May 27, 2026, 8:52:18 AM	Sweden	5/26/2026		Notification	Registration of Invoicing Details for Economic Operators Reg...	P1	UDI/device registration
South Africa_May 28, 2026, 8:49:06 AM	South Africa	5/26/2026	5/26/2026	Guidance	Guideline on How to Respond to a GMP, GWP, GCP or GVP Inspec...	No SB action	QMS/GMP evidence
India_May 28, 2026, 4:37:20 AM	India	5/26/2026	5/26/2026	Circular	Regulatory Guidelines for Sampling of Drugs, Cosmetics & Med...	No SB action	QMS/GMP evidence
Korea_May 28, 2026, 2:45:56 PM	Korea	5/28/2026	5/28/2026	Guidance	FAQs for Medical Device Non-clinical Trials Guidance	P2	Product-specific technical evidence
Spain_May 28, 2026, 8:53:56 AM	Spain	5/27/2026	6/15/2026	Notification	Launch of RECOPS, the New Application for the Marketing Regi...	P1	Registration dossier
Denmark_May 28, 2026, 9:33:55 AM	Denmark	5/28/2026	Notification	Notification	Registration Fee	No SB action	Fees and admini...
Denmark_May 28, 2026, 9:37:25 AM	Denmark	5/27/2026		Notification	Distributor and Specialist Store Registration	No SB action	UDI/device registration
Denmark_May 28, 2026, 9:50:51 AM	Denmark	5/28/2026		Notification	Registration	P1	UDI/device registration
Denmark_May 28, 2026, 9:53:42 AM	Denmark	5/28/2026		Notification	Registration in Eudamed	P1	UDI/device registration
Czech Republic_May 28, 2026, 10:09:57 AM	Czech Republic	5/27/2026		Notification	Temporary Retention of FSC Applications through RZPRO	P2	Registration dossier
Colombia_May 29, 2026, 2:03:58 PM	Colombia	5/28/2026	6/4/2026	Announcement	Invima Hosts a Conference on Healthcare Technologies from a ...	No SB action	Registration dossier

Tanzania_Jun 1, 2026, 4:04:02 AM	Tanzania	5/31/2026	5/31/2026	Notification	Explanation of the Challenges of the New Joint Load Relief S...	No SB action	Registration dossier
Cameroon_Jun 1, 2026, 4:52:19 AM	Cameroon	5/29/2026	5/29/2026	Circular	Implementation of a combined Individual Case Safety Report (...)	No SB action	Registration dossier
Iraq_Jun 1, 2026, 6:42:00 AM	Iraq	5/31/2026	6/1/2026	Circular	Announcement from the Pharmacy Department, Private Sector Di...	No SB action	Registration dossier
Singapore_May 29, 2026, 4:36:56 AM	Singapore	5/28/2026	5/28/2026	Announcement	How Medical Devices are Regulated by HSA and their Safe Use	No SB action	Registration dossier
United States_May 29, 2026, 5:12:01 AM	United States	5/28/2026	5/29/2026	Guidance	Content of Human Factors Information in Medical Device Marke...	No SB action	Registration dossier
Belgium_May 29, 2026, 5:34:31 AM	Belgium	5/28/2026	5/28/2026	Notification	EUDAMED: Clarifications Regarding Obligations as of 28 May 2...	P1	UDI/device registration
Slovenia_May 29, 2026, 6:07:36 AM	Slovenia	5/13/2026	5/13/2026	General informative document	Q&A Education May 13, 2026: Obligations of Distributors and ...	No SB action	Registration dossier
Denmark_Jun 1, 2026, 5:10:11 AM	Denmark	5/28/2026		Notification	Annual Fee	No SB action	Fees and admini...
Brazil_Jun 2, 2026, 11:42:47 AM	Brazil	6/1/2026	6/1/2026	Guidance	Guidance: Importation via DUIMP_v1.9	P2	Import authorization
Argentina_Jun 2, 2026, 3:02:56 PM	Argentina	6/1/2026	6/1/2026	Announcement	Update on fees for ANMAT procedures	No SB action	Fees and admini...
United States_Jun 2, 2026, 4:31:04 AM	United States	6/1/2026	8/1/2026	Guidance	eSTAR Program	P1	Registration dossier
Czech Republic_Jun 2, 2026, 10:01:47 AM	Czech Republic	6/1/2026	6/1/2026	Guideline	Methodological Guideline for the Implementation of MDR Requi...	P2	Registration dossier
Syria_Jun 3, 2026, 6:09:04 AM	Syria	6/3/2026	6/3/2026	Regulation	Regulatory Decision 8/T	No SB action	Registration dossier
Oman_Jun 3, 2026, 6:38:07 AM	Oman	6/3/2026	6/3/2026	Regulation	Requirements for Approval of Optical Companies Applying for ...	No SB action	Registration dossier
Iraq_Jun 3, 2026, 9:39:07 AM	Iraq	6/3/2026	6/7/2026	Circular	Circular No. 9/2/1163 To All Scientific Offices and National...	No SB action	Registration dossier
United States_Jun 3, 2026, 5:21:20 AM	United States	6/2/2026		Draft	Drug and Device Manufacturer Communications With Payors, For...	Watchlist	Registration dossier
Switzerland_Jun 3, 2026, 5:54:02 AM	Switzerland	6/2/2026	6/2/2026	Guidance	Swissdamed Business Rules	P1	UDI/device registration
Uzbekistan_Jun 2, 2026, 12:43:36 PM	Uzbekistan	5/27/2026	6/1/2026	General alert	New legislative changes will come into force in Uzbekistan o...	No SB action	Registration dossier
Uzbekistan_Jun 2, 2026, 12:48:35 PM	Uzbekistan	5/5/2026	5/7/2026	President's Decree	On measures to provide additional support to the private sec...	No SB action	Registration dossier
Singapore_Jun 3, 2026, 4:35:05 AM	Singapore	6/2/2026	6/2/2026	Guidance	GN-12-1: Guidance on Grouping of Medical Devices for Product...	P2	Grouping

South Africa_Jun 4, 2026, 1:35:27 PM	South Africa	6/4/2026	6/4/2026	Guidance	Regulatory Requirements for Medical Devices Electronic Instr...	P2	Labeling/IFU
Uzbekistan_Jun 4, 2026, 11:51:44 AM	Uzbekistan	5/25/2026	6/3/2026	Legal act	Departmental regulatory legal act on the procedure for condu...	P2	Registration dossier
Germany_Jun 5, 2026, 3:50:38 AM	Germany	5/28/2026	5/28/2026	News	European Database for Medical Devices: EUDAMED	P1	UDI/device registration
Germany_Jun 5, 2026, 4:02:06 AM	Germany	5/28/2026	5/28/2026	General information	Instructions for those Required to Report Address Ads	No SB action	Fees and admin
Germany_Jun 5, 2026, 4:10:08 AM	Germany	5/28/2026	5/28/2026	Notification	May 28, 2026: Initial and Amendment Notification MP and IVD	P1	UDI/device registration
United States_Jun 5, 2026, 8:40:40 AM	United States	6/5/2026		Guidance	Intent to Exempt Certain Unclassified Medical Devices from P...	P2	Classification
Australia_Jun 8, 2026, 7:02:02 AM	Australia	6/3/2026	N/A	Guidance	Annual charge waiver guidelines - How to apply for an annual...	No SB action	Registration dossier
Srilanka_Jun 8, 2026, 7:07:22 AM	Srilanka	5/21/2026	N/A	Notification	Reissuance of Sample Import License (SIL)- Medical Devices	No SB action	Registration dossier
Srilanka_Jun 8, 2026, 7:09:35 AM	Srilanka	5/21/2026	7/7/2026	Notification	Checklist for Document Accepting of Consolidated new Medical...	No SB action	Registration dossier
Algeria_Jun 8, 2026, 10:56:20 AM	Algeria	5/31/2026	5/31/2026	Guidance	Regulatory Inspections Guideline	No SB action	QMS/GMP evidence
Algeria_Jun 8, 2026, 10:57:37 AM	Algeria	5/13/2026	5/13/2026	Guidance	Guidelines for Regulatory Trust (Reliance) and Recognition P...	P2	Registration dossier
Bolivia_Jun 9, 2026, 1:29:07 PM	Bolivia	6/8/2026	6/8/2026	Circular	Cyber Attack at AGEMED Systems	No SB action	Registration dossier
Nicaragua_Jun 9, 2026, 1:34:15 PM	Nicaragua	6/8/2026	6/8/2026	Regulation	Public Consultation 175 - (NTON) 24001	No SB action	Registration dossier
Lebanon_Jun 9, 2026, 2:42:46 PM	Lebanon	6/9/2026	8/9/2026	Circular	Circular No. 22 Regarding the Entry of Import Invoices for N...	No SB action	Import authorization
Lebanon_Jun 9, 2026, 2:47:58 PM	Lebanon	6/9/2026	6/9/2026	Circular	Circular No. 23 Regarding FDA-Approved Implantable Medical D...	No SB action	Import authorization
Switzerland_Jun 9, 2026, 6:24:07 AM	Switzerland	6/8/2026	6/5/2026	Guidance	Swissdamed Machine-to-Machine REST API Technical Documentati...	P1	Registration dossier
Qatar_Jun 10, 2026, 9:54:59 AM	Qatar	6/9/2026	6/9/2026	Announcement	Customs Union Authority Launches "Taysir" System to Address ...	No SB action	Registration dossier
Botswana_Jun 10, 2026, 10:33:33 AM	Botswana	6/10/2026	7/1/2026	Notice	Notice of Implementation of a Combined Screening and Evaluat...	No SB action	Registration dossier
Germany_Jun 10, 2026, 3:48:38 AM	Germany	6/9/2026	6/5/2026	News notification	Self-declaration Regarding the Implementation of the Require...	No SB action	Fees and admin
Latvia_Jun 10, 2026, 4:10:40 AM	Latvia	5/28/2026	5/28/2026	News notification	EUDAMED, The European Database for Medical Devices, Launches	P1	UDI/device registration

Latvia_Jun 10, 2026, 4:18:12 AM	Latvia	6/9/2026		News	The Government Supports the Consolidation of Supervision of ...	No SB action	Registration dossier
Luxembourg_Jun 10, 2026, 4:49:23 AM	Luxembourg	5/28/2026	5/28/2026	Medical Device news	Mandatory use of EUDAMED from May 28, 2026	P1	UDI/device registration
China_Jun 11, 2026, 2:37:51 AM	China	6/3/2026	6/3/2026	Draft for Comment	China NMPA Seeks Public Input on Four Draft Medical Device R...	Watchlist	Product-specific technical evidence
China_Jun 11, 2026, 2:46:33 AM	China	6/10/2026	6/10/2026	Draft for Comment	China NMPA Opens Public Consultation on Draft Registration R...	Watchlist	Product-specific technical evidence
China_Jun 11, 2026, 2:54:05 AM	China	6/1/2026	6/1/2026	Notification	China NMPA Issues Announcement on Medical Device Classificat...	P2	Classification
Singapore_Jun 11, 2026, 4:32:35 AM	Singapore	6/11/2026	6/11/2026	Notification	Mean Applicant Screening Response Time Audiences	No SB action	Registration dossier
South Africa_Jun 11, 2026, 9:58:10 AM	South Africa	6/10/2026	6/10/2026	Guidance	Guideline on Minimum Requirements for Inspecting Group III a...	P2	Registration dossier
South Africa_Jun 11, 2026, 10:00:11 AM	South Africa	6/11/2026	6/11/2026	Guidance	Application for Authority for the Temporary Use, Possession ...	No SB action	Registration dossier
Kazakhstan_Jun 11, 2026, 11:09:46 AM	Kazakhstan	6/10/2026	6/25/2026	Draft Order	On amendments to the order of the Minister of Health of the ...	Watchlist	Fees and admin
Algeria_Jun 11, 2026, 12:02:58 PM	Algeria	6/11/2026		Notice	Note to Pharmaceutical Institutions	No SB action	Fees and admin
Lithuania_Jun 11, 2026, 4:28:41 AM	Lithuania	6/10/2026		News	Information Regarding a Cyber Incident	No SB action	Registration dossier
Lithuania_Jun 11, 2026, 4:33:25 AM	Lithuania	6/10/2026		News	VASPV T Informs About the Controlled Cyber Incident in the In...	No SB action	Registration dossier
Hungary_Jun 12, 2026, 4:55:23 AM	Hungary	6/10/2026		Notification	Deviation from Conformity Assessment Procedures	P2	Registration dossier
Hungary_Jun 12, 2026, 4:58:54 AM	Hungary	6/10/2026		Notification	Conformity Assessment Bodies	P2	Registration dossier
United Kingdom_Jun 12, 2026, 6:22:09 AM	United Kingdom	6/11/2026	6/11/2026	Guidance	Regulation of Medical Devices in Northern Ireland	P2	Registration dossier
Korea_Jun 14, 2026, 9:42:19 PM	Korea	6/10/2026	6/10/2026	Guidance	Labeling Guideline for Digital Medical Devices	P2	Classification
Korea_Jun 14, 2026, 9:44:03 PM	Korea	6/12/2026	TBD	Draft	Medical Device Manufacturing and Quality Control Standards	P2	Registration dossier
Hong Kong_Jun 15, 2026, 9:01:00 AM	Hong Kong	6/12/2026	6/12/2026	Guidance	GN-02: Guidance Notes for Listing Class II/III/IV General Me...	P2	Registration dossier
Hong Kong_Jun 15, 2026, 9:02:26 AM	Hong Kong	6/12/2026	6/12/2026	Guidance	GN-06: Guidance Notes for Listing Class B/C/D In Vitro Diagn...	P2	Registration dossier
Brazil_Jun 15, 2026, 4:31:55 PM	Brazil	6/12/2026	6/12/2026	Circular	ANVISA Expands Support and Improvement Measures to Support t...	P2	Import authorization

Norway_Jun 15, 2026, 5:02:09 AM	Norway	6/12/2026		News	Medical Device Supervision Shows Challenges with Cosmetic Cl...	No SB action	Registration dossier
Kyrgyzstan_Jun 15, 2026, 12:55:27 PM	Kyrgyzstan	6/8/2026	6/18/2026	Government's Decree	On Amendments to the Resolution of the Cabinet of Ministers ...	P2	Registration dossier
United States_Jun 16, 2026, 11:30:56 AM	United States	6/16/2026	6/16/2026	TESTING	TESTING ISSUES	No SB action	Fees and admin
China_Jun 17, 2026, 2:05:08 AM	China	6/5/2026	6/5/2026	Notification	China's NMPA Announces Removal of 10 Medical Device Industry...	P2	Product-specific technical evidence
Mexico_Jun 17, 2026, 3:39:23 PM	Mexico	6/17/2026	6/17/2026	Guidance	Cofepris has published an update to the Guide to Requirement...	P2	Registration dossier
Australia_Jun 18, 2026, 9:31:14 AM	Australia	6/18/2026	N/A	Guidance	TGA Releases New Guidance on Advertising Restrictions for Pr...	No SB action	Registration dossier
Peru_Jun 18, 2026, 4:37:01 PM	Peru	6/17/2026	6/25/2026	Announcement	Announcement No. 008/2026 - Webinar on the Medical Device Ri...	No SB action	Registration dossier
Canada_Jun 18, 2026, 3:42:55 AM	Canada	6/17/2026	12/14/2026	Bulletin	Phase 2 of our Work to Modernize Medical Device Establishmen...	P1	Registration dossier
South Africa_Jun 19, 2026, 4:40:26 AM	South Africa	6/15/2026	6/15/2026	Guidance	Guideline on Minimum Requirements for Inspecting Group III a...	P2	Registration dossier
Saudi Arabia_Jun 19, 2026, 11:42:41 AM	Saudi Arabia	6/18/2026	11/1/2026	Announcement	Standard Specification Annex No. (1) of the Technical Regula...	P1	Registration dossier
Costa Rica_Jun 19, 2026, 2:26:44 PM	Costa Rica	6/18/2026	7/1/2026	Announcement	Digital systems will be temporarily out of service	No SB action	Registration dossier
Belarus_Jun 19, 2026, 4:12:34 AM	Belarus	6/16/2026	6/30/2026	Notification	Transfer of Medical Device Regulatory Functions in Belarus	No SB action	Registration dossier
Switzerland_Jun 19, 2026, 5:37:40 AM	Switzerland	6/18/2026	6/15/2026	Guidance	Swissdamed User Manual Actors	P1	Registration dossier
Rwanda_Jun 22, 2026, 8:37:42 AM	Rwanda	6/18/2026	6/18/2026	Regulation	Regulations Governing Good Manufacturing Practices of Medica...	No SB action	Registration dossier
Bolivia_Jun 22, 2026, 3:05:41 PM	Bolivia	6/22/2026	6/17/2026	Circular	AGEMED/CE/021/2026	No SB action	Registration dossier
Bolivia_Jun 22, 2026, 3:18:01 PM	Bolivia	6/22/2026	6/16/2026	Circular	MSyD/AGEMED/CR/19/2026	No SB action	Registration dossier
Botswana_Jun 22, 2026, 6:47:11 PM	Botswana	6/18/2026		Announcement	BOMRA Medical Devices, including IVDs, Regulatory Update: Me...	No SB action	Registration dossier
Switzerland_Jun 22, 2026, 4:54:45 AM	Switzerland	6/19/2026		Notification	New Options for Product Registration in Swissdamed: Online E...	P1	Registration dossier
Switzerland_Jun 22, 2026, 4:58:30 AM	Switzerland	6/19/2026	7/1/2026	Notification	Amendment to the Swissmedic Fee Ordinance as of July 1, 2026	No SB action	Fees and admin
Switzerland_Jun 22, 2026, 5:52:18 AM	Switzerland	6/19/2026	5/19/2026	Guidance	Procurement of Medical Devices in Healthcare Facilities	P1	Registration dossier

Switzerland_Jun 22, 2026, 6:06:00 AM	Switzerland	6/19/2026	6/19/2026	Guidance	Swissdamed User Guide - Playground	P1	Registration dossier
Switzerland_Jun 22, 2026, 6:14:07 AM	Switzerland	6/19/2026	6/19/2026	Guidance	User Manual Swissdamed UDI Device Module	P1	Registration dossier
Sweden_Jun 22, 2026, 9:55:06 AM	Sweden	6/17/2026		News	The Swedish Medicines Agency will be responsible for AI syst...	Watchlist	Classification
European Union_Jun 22, 2026, 10:11:14 AM	European Union	6/17/2026		Guidance	Guidance on standardisation for medical devices	P2	Product-specific technical evidence
European Union_Jun 22, 2026, 10:34:29 AM	European Union	6/18/2026		Guidance	MDCG Position Paper: Management of SS(C)P in EUDAMED after m...	P1	UDI/device registration
Bahrain_Jun 23, 2026, 4:06:24 PM	Bahrain	6/9/2026	6/9/2026	Circular	Updated Fee Schedules of Services and Requests for Medical D...	No SB action	Fees and admin
Mexico_Jun 23, 2026, 4:29:40 PM	Mexico	6/22/2026	6/19/2026	Announcement	Update on the Reliance Regulatory Fast Track Platform	No SB action	Fees and admin
Korea_Jun 23, 2026, 10:30:23 AM	Korea	6/23/2026	7/1/2026	Enforcement Decree	Enforcement Decree of the Medical Device Act	P2	Registration dossier
Australia_Jun 24, 2026, 5:57:33 AM	Australia	6/22/2026	N/A	Notification	New UDI Newsletter	P2	UDI/device registration
Australia_Jun 24, 2026, 6:01:28 AM	Australia	6/22/2026	N/A	Notification	Getting started with UDI	P2	UDI/device registration
Australia_Jun 24, 2026, 6:05:33 AM	Australia	6/24/2026	N/A	Guidance	Complying with the Unique Device Identification timeframes f...	P2	UDI/device registration
Australia_Jun 24, 2026, 6:10:20 AM	Australia	6/24/2026	N/A	Notification	Unique Device Identification Consent to Supply process	No SB action	Registration dossier
Brazil_Jun 24, 2026, 1:47:47 PM	Brazil	6/23/2026	6/23/2026	Circular	ANVISA Opens Public Call for Proposals to Improve Technovigi...	No SB action	Registration dossier
Denmark_Jun 24, 2026, 4:45:59 AM	Denmark	6/18/2026		Notification	Fees for Clinical Trials of Medical Devices	No SB action	Fees and admin
Kyrgyzstan_Jun 25, 2026, 9:35:32 AM	Kyrgyzstan	6/25/2026	7/17/2026	Draft	Government's Decree	Watchlist	Fees and admin
Kazakhstan_Jun 25, 2026, 2:07:51 PM	Kazakhstan	6/24/2026	6/24/2026	Law	Law of Kazakhstan On Amendments and Supplements to Certain ...	No SB action	Registration dossier
South Africa_Jun 25, 2026, 12:06:47 PM	South Africa	6/25/2026	6/25/2026	Guidance	Communication on Research Use Only (RUO) and Investigational...	P1	Registration dossier
China_Jun 26, 2026, 3:47:34 AM	China	6/17/2026	6/17/2026	Draft for Comment	China's NMPA Invites Industry Participation in Drafting Regi...	Watchlist	Product-specific technical evidence
China_Jun 26, 2026, 3:49:36 AM	China	6/23/2026	6/23/2026	Guidance	China's NMPA Issues 2026 Revised Registration Review Guideli...	P2	Product-specific technical evidence
China_Jun 26, 2026, 3:51:53 AM	China	6/18/2026	6/18/2026	Notification	China's NMPA Releases Technical Review Guidelines for Varico...	P2	Product-specific technical evidence

China_Jun 26, 2026, 3:53:43 AM	China	6/15/2026	6/15/2026	Notification	China's NMPA Issues Trial Technical Review Guidelines for Tu...	P2	Product-specific technical evidence
India_Jun 26, 2026, 4:08:23 AM	India	6/24/2026	6/24/2026	Circular	Sale of In-Vitro Fertilization Media, Reagents, and Related ...	No SB action	QMS/GMP evidence
Korea_Jun 26, 2026, 5:57:20 AM	Korea	6/23/2026	7/1/2026	Guidance	Enforcement Decree of the Medical Device Act	P2	Registration dossier
Bolivia_Jun 26, 2026, 12:30:37 PM	Bolivia	6/25/2026	6/25/2026	Circular	CIRCULAR-22-2026	No SB action	Registration dossier
Brazil_Jun 26, 2026, 12:34:24 PM	Brazil	6/25/2026	6/25/2026	Regulation	TECHNICAL NOTE Nº 41/2026/SEI/GQUIP/GGTPS/DIRE3/ANVISA	No SB action	Registration dossier
Kuwait_Jun 26, 2026, 7:30:46 PM	Kuwait	6/13/2026	6/13/2026	User Manual	Electronic Invoice Release Platform Companies` User Manual	No SB action	Registration dossier
Korea_Jun 26, 2026, 2:00:10 PM	Korea	6/26/2026	6/26/2026	Guidance	Approval and Review Guideline for Digital Medical Device Cha...	P2	Classification
Kyrgyzstan_Jun 28, 2026, 1:21:50 AM	Kyrgyzstan	6/18/2026	6/28/2026	Resolution of the Cabinet of Ministers of Kyrgyzstan	On Amendments to the Resolution of the Government of the Kyr...	No SB action	Registration dossier
Oman_Jun 29, 2026, 5:20:32 AM	Oman	6/28/2026	6/28/2026	Circular	Extension of Registration Period for High-Risk Medical Devic...	P2	Registration dossier
MISSING-01	Malaysia	2026-05-01 (est.)	2026-08-01	Announcement	Fully Online Product Classification Application (effective A...	P1	Classification
MISSING-02	United Kingdom	2026-06-01 (est.)	2026-06-01 (est.)	Guidance	Updated Clinical Investigation Submission Guidance (IRAS)	P2	Clinical investigation
MISSING-03	European Union	2026-04-01 (est.)	2026-04-01 (est.)	Guidance	MDCG 2026-5: UDI Assignment Between Manufacturers and Distri...	P2	UDI/device registration
MISSING-04	South Africa	2026-06-01 (est.)	2026-06-01 (est.)	Application Form	GLF-MD-25A: Updated RUO/IUO Application Form	P1	Registration dossier

Methodology & Limitations

Two-Field Assessment Model

Each alert is assessed on two separate dimensions: (A) **Regulated-party impact** — what the manufacturer or economic operator must do, and (B) **SB wizard impact** — whether a wizard, pathway, dossier requirement, application form, conditional logic, source file, or generated output must change. These are independent assessments. Manufacturer urgency does not equal SB implementation urgency.

SB Priority Framework

Priority	Definition
P0 – Release blocker	Current or imminent requirement makes an active wizard materially incorrect, unusable, or incapable of generating an acceptable submission
P1 – Confirmed update	Final requirement affects a released wizard and should be implemented promptly
P2 – Scheduled review	Relevant clarification, future requirement, or lower-risk content change requiring review before next release cycle
Watchlist	Draft, consultation, or unverified revision; no implementation until final publication and delta confirmed
No SB action	Operational, post-market, fee, enforcement, or business-compliance alert outside wizard scope

Confidence Levels

Level	Meaning
High	Official source confirmed; regulatory delta clearly identified; SB impact well-defined
Medium	Source confirmed; delta partially identified or requires document comparison; SB impact directionally clear
Low	Source not independently verified; delta unknown; wizard baseline not available for comparison; or version-history uncertain

Known Limitations

- **Wizard baseline unavailable:** Current SB wizard content and source file versions were not accessible for direct field-level comparison. All SB impact assessments marked "Pending human validation."
- **EUDAMED XSD/data model:** Mandatory-use date alone does not confirm an XSD or data-format change. Technical specification review required before concluding output format changes are needed.
- **Ethiopia EFDA guidance:** Confidence LOW — some EFDA device guidance predates 2026; July 2026 publication may reflect migration or republication of existing content, not a substantive regulatory change. Version-history verification required.
- **Data cut-off:** July 29, 2026. Alerts published July 30–31 are not captured in this report.
- **4 missing alerts:** Malaysia online Product Classification, UK clinical investigation guidance (IRAS), MDCG 2026-5, and South Africa GLF-MD-25A were added based on independent research and should be verified against official sources before implementation.
- **Validation status:** All assessments are marked "Pending human validation." No SB implementation should proceed without review by the responsible wizard owner.

Recommended next step: For each P1 alert, assign a wizard owner, set a due date, and perform direct comparison of the official source document against the current wizard baseline before initiating any implementation. For EUDAMED, Swissdamed, and FDA eSTAR, obtain the official technical specifications (XSD, data dictionary, source PDF) before modifying export logic.