

Submission Builder Impact Assessment

Medical Devices, IVDs & Combination Devices
May – July 2026

Assessment date: July 29, 2026 · Data cut-off: July 29, 2026

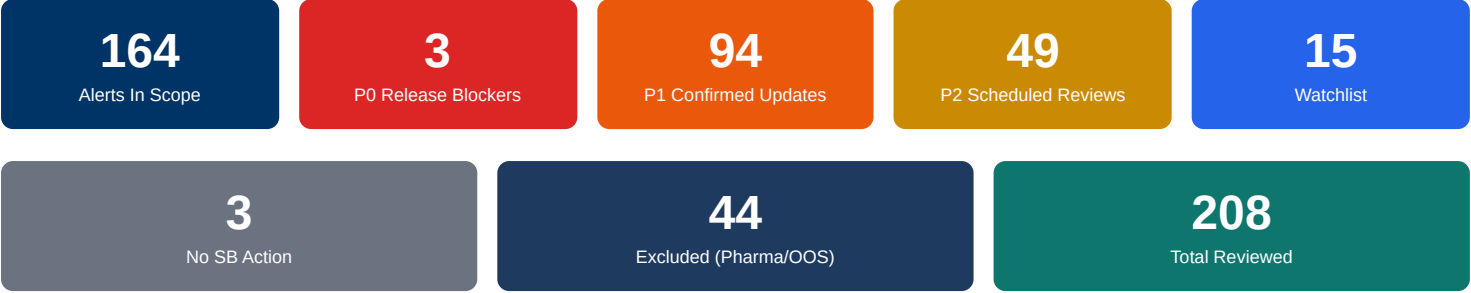
Scope & Methodology

This report assesses 164 regulatory alerts across 60+ markets to determine their specific impact on Submission Builder wizards. Each alert receives two separate evaluations: *regulated-party impact* (what manufacturers must do) and *SB impact* (what wizards must change). Pharma-only alerts (44 total) are listed in the Annex. Priority follows the SB priority model: P0 Release blocker → P1 Confirmed update → P2 Scheduled review → Watchlist → No SB action.

Executive Summary

Alert Counts · Priority Distribution · Top Actions
Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

Alert Overview



Top 5 Highest-Priority SB Actions

Alert ID	Market	Alert	Priority	Action
SB-2026-073	Spain	Launch of RECOPS, the New Application for the Marketing Registration o	P0	Implement
SB-2026-081	United States	Content of Human Factors Information in Medical Device Marketing Submi	P0	Implement
SB-2026-086	United States	eSTAR Program	P0	Implement
SB-2026-001	Malaysia	Joint Announcement by Medical Device Authority (MDA) Malaysia and Thai	P1	Monitor
SB-2026-002	Turkey	Mandatory Use of the EUDAMED Database System (Law No. 2026/KKB-1) and	P1	Compare

Markets with Most In-Scope Alerts

Country	Count
Australia	13
Switzerland	13
China	13
Korea	7
Mexico	6
Kazakhstan	6
Denmark	5
Serbia	5
United States	4
Malaysia	4
Nicaragua	4
United Kingdom	4
Czech Republic	4
Brazil	4
Turkey	3

SB Priority Framework

Priority	Definition
P0	Active wizard is materially incorrect, unusable or cannot generate an acceptable submission
P1	Final requirement affects a released wizard; implement promptly
P2	Relevant clarification or lower-risk content change; schedule review
Watchlist	Draft, consultation or unverified revision; no implementation yet
No SB action	Operational, post-market, admin or business-compliance alert outside wizard scope

Impact Taxonomy

Category
No SB impact
Instructions/reference update
Existing wizard content update
Conditional logic or pathway update
Official form/source-template update
Export/XML/data-mapping update
New wizard or coverage-gap assessment
Manual technical review
Watchlist—draft or unverified

SB Action Dashboard

All In-Scope Alerts · Prioritized · 164 Alerts

Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

Alert ID	Market	Published	Alert (abbreviated)	Priority	Impact Category	Action	Confidence
SB-2026-073	Spain	5/27/2026	Launch of RECOPS, the New Application for the Marketing	P0	Conditional logic or pathway u	Implement	High
SB-2026-081	United States	5/28/2026	Content of Human Factors Information in Medical Device	P0	Existing wizard content update	Implement	High
SB-2026-086	United States	6/1/2026	eSTAR Program	P0	Existing wizard content update	Implement	High
SB-2026-001	Malaysia	5/1/2026	Joint Announcement by Medical Device Authority (MDA) Ma	P1	Conditional logic or pathway u	Monitor	Medium
SB-2026-002	Turkey	5/4/2026	Mandatory Use of the EUDAMED Database System (Law No. 2	P1	Instructions/reference update	Compare	Medium
SB-2026-007	Australia	5/4/2026	Accessing and using the AusUDID	P1	Existing wizard content update	Compare	High
SB-2026-008	Australia	5/4/2026	AusUDID submission methods	P1	Existing wizard content update	Compare	High
SB-2026-009	Australia	5/4/2026	Accessing the AusUDID	P1	Instructions/reference update	Compare	Medium
SB-2026-010	Australia	5/4/2026	AusUDID data elements	P1	Existing wizard content update	Compare	High
SB-2026-011	Saudi Arabia	5/5/2026	Guidance on Bundling Criteria for Medical Devices withi	P1	Existing wizard content update	Compare	High
SB-2026-014	Spain	5/4/2026	The AEMPS Updates the Information on the Medical Device	P1	Instructions/reference update	Compare	Medium
SB-2026-016	European Union	5/5/2026	Implementing Regulation (EU) 2026/977 – Uniform Require	P1	Existing wizard content update	Compare	High
SB-2026-017	Denmark	5/5/2026	Medical Devices with Incorporated Drug	P1	Conditional logic or pathway u	Compare	High
SB-2026-020	Saudi Arabia	5/5/2026	SFDA Medical Devices Forms Updates	P1	Official form/source-template	Implement	High
SB-2026-021	Turkey	5/7/2026	TCOKKA - Publication of Implementing Regulation (EU) 20	P1	Existing wizard content update	Compare	High
SB-2026-022	Australia	5/11/2026	Using assessments from comparable overseas regulators f	P1	Conditional logic or pathway u	Compare	High
SB-2026-023	Australia	5/11/2026	Use of market authorisation evidence from comparable ov	P1	Conditional logic or pathway u	Compare	High
SB-2026-024	Switzerland	5/10/2026	Swissdamed User Manual Actors	P1	Existing wizard content update	Implement	High
SB-2026-026	Algeria	5/11/2026	Note No. 42 to Pharmaceutical Establishment Relating to	P1	Existing wizard content update	Compare	Low
SB-2026-028	Egypt	5/14/2026	Regulatory Guideline on Requirements for Unique Device	P1	Existing wizard content update	Compare	High
SB-2026-030	Nicaragua	5/13/2026	New Importation/Exportation Form	P1	Official form/source-template	Implement	High
SB-2026-033	United Kingdom	5/13/2026	Medical Devices: Conformity Assessment and the UKCA Mar	P1	Existing wizard content update	Compare	High
SB-2026-035	Bahrain	5/13/2026	Launch of TATABU Medical Devices & Supplies Traceabilit	P1	New wizard or coverage-gap ass	Monitor	Medium
SB-2026-037	Malaysia	5/15/2026	Requirements for Labelling of Medical Devices	P1	Existing wizard content update	Compare	High
SB-2026-038	Malaysia	5/15/2026	Change Management for Registered Medical Devices	P1	Existing wizard content update	Compare	High
SB-2026-039	Ecuador	5/18/2026	ARCSA has published Resolution ARCSA-DE-2026-003-DASP -	P1	Existing wizard content update	Compare	Medium

SB-2026-041	Nicaragua	5/15/2026	User Guide for Requesting the Issuance of a Registratio	P1	Instructions/reference update	Compare	Medium
SB-2026-042	Nicaragua	5/15/2026	New Official Request Form for Health Registration Certi	P1	Official form/source-template	Implement	High
SB-2026-043	Vietnam	5/15/2026	Notice on Domain Change for the Online Public Service P	P1	Instructions/reference update	Implement	High
SB-2026-046	United Kingdom	5/14/2026	Clinical Investigations for Medical Devices	P1	Existing wizard content update	Compare	High
SB-2026-047	Serbia	5/15/2026	New Conditions and Methods of Recognition of Foreign Do	P1	Conditional logic or pathway u	Compare	High
SB-2026-048	Serbia	5/15/2026	New Conditions and Methods of Recognition of Foreign Ce	P1	Conditional logic or pathway u	Compare	High
SB-2026-049	Serbia	5/15/2026	New Conditions and Methods of Recognition of Foreign Do	P1	Conditional logic or pathway u	Compare	High
SB-2026-050	Serbia	5/15/2026	New Conditions and Methods of Recognition of Foreign Ce	P1	Conditional logic or pathway u	Compare	High
SB-2026-051	Serbia	5/15/2026	Instructions for Submitting a Request for Amendment/Add	P1	Existing wizard content update	Compare	High
SB-2026-052	Czech Republic	5/18/2026	Application for Authorization to place a Medical Device	P1	Existing wizard content update	Compare	High
SB-2026-053	Mexico	5/19/2026	Cofepris has published Mexican Official Standard NOM-13	P1	Existing wizard content update	Implement	High
SB-2026-060	Peru	5/21/2026	DIGEMID has published Ministerial Resolution No. 193-20	P1	Existing wizard content update	Compare	Low
SB-2026-062	Australia	5/22/2026	Complying with the Unique Device Identification timefra	P1	Instructions/reference update	Compare	Medium
SB-2026-065	Czech Republic	5/18/2026	Methodological Instructions for Submitting an Applicati	P1	Existing wizard content update	Compare	High
SB-2026-066	Sweden	5/25/2026	Regulations (HSLF-FS 2026:11) amending the Medical Prod	P1	Existing wizard content update	Compare	High
SB-2026-067	Portugal	5/20/2026	Operationalization of EUDAMED on May 28, 2026	P1	Instructions/reference update	Compare	High
SB-2026-074	Denmark	5/27/2026	Distributor and Specialist Store Registration	P1	Existing wizard content update	Compare	Medium
SB-2026-076	Denmark	5/28/2026	Registration in Eudamed	P1	Instructions/reference update	Compare	Medium
SB-2026-077	Czech Republic	5/27/2026	Temporary Retention of FSC Applications through RZPRO	P1	Instructions/reference update	Compare	Medium
SB-2026-082	Belgium	5/28/2026	EUDAMED: Clarifications Regarding Obligations as of 28	P1	Existing wizard content update	Compare	High
SB-2026-083	Slovenia	5/13/2026	Q&A Education May 13, 2026: Obligations of Distributors	P1	Existing wizard content update	Compare	Medium
SB-2026-084	Brazil	6/1/2026	Guidance: Importation via DUIMP_v1.9	P1	Instructions/reference update	Compare	High
SB-2026-087	Czech Republic	6/1/2026	Methodological Guideline for the Implementation of MDR	P1	Existing wizard content update	Compare	High
SB-2026-089	Oman	6/3/2026	Requirements for Approval of Optical Companies Applying	P1	Existing wizard content update	Compare	Medium
SB-2026-091	Switzerland	6/2/2026	Swissdamed Business Rules	P1	Existing wizard content update	Compare	High
SB-2026-092	Uzbekistan	5/27/2026	New legislative changes will come into force in Uzbekis	P1	Existing wizard content update	Compare	Medium
SB-2026-094	Singapore	6/2/2026	GN-12-1: Guidance on Grouping of Medical Devices for Pr	P1	Conditional logic or pathway u	Compare	High
SB-2026-095	South Africa	6/4/2026	Regulatory Requirements for Medical Devices Electronic	P1	Existing wizard content update	Compare	High
SB-2026-097	Germany	5/28/2026	European Database for Medical Devices: EUDAMED	P1	Instructions/reference update	Compare	Medium

SB-2026-098	Germany	5/28/2026	May 28, 2026: Initial and Amendment Notification MP and	P1	Existing wizard content update	Compare	Medium
SB-2026-100	Srilanka	5/21/2026	Reissuance of Sample Import License (SIL)- Medical Device	P1	Existing wizard content update	Compare	Medium
SB-2026-101	Srilanka	5/21/2026	Checklist for Document Accepting of Consolidated new Me	P1	Official form/source-template	Implement	High
SB-2026-102	Algeria	5/13/2026	Guidelines for Regulatory Trust (Reliance) and Recognit	P1	Conditional logic or pathway u	Compare	Medium
SB-2026-105	Lebanon	6/9/2026	Circular No. 23 Regarding FDA-Approved Implantable Medi	P1	Existing wizard content update	Compare	High
SB-2026-107	Germany	6/9/2026	Self-declaration Regarding the Implementation of the Re	P1	Existing wizard content update	Compare	Medium
SB-2026-108	Latvia	5/28/2026	EUDAMED, The European Database for Medical Devices, Lau	P1	Instructions/reference update	Compare	Low
SB-2026-109	Luxembourg	5/28/2026	Mandatory use of EUDAMED from May 28, 2026	P1	Instructions/reference update	Compare	Low
SB-2026-112	China	6/1/2026	China NMPA Issues Announcement on Medical Device Classi	P1	Conditional logic or pathway u	Compare	High
SB-2026-115	Hungary	6/10/2026	Deviation from Conformity Assessment Procedures	P1	Existing wizard content update	Compare	Medium
SB-2026-116	Hungary	6/10/2026	Conformity Assessment Bodies	P1	Existing wizard content update	Compare	Medium
SB-2026-117	United Kingdom	6/11/2026	Regulation of Medical Devices in Northern Ireland	P1	Existing wizard content update	Compare	High
SB-2026-118	Korea	6/10/2026	Labeling Guideline for Digital Medical Devices	P1	Existing wizard content update	Compare	High
SB-2026-120	Hong Kong	6/12/2026	GN-02: Guidance Notes for Listing Class II/III/IV Gener	P1	Existing wizard content update	Compare	High
SB-2026-121	Hong Kong	6/12/2026	GN-06: Guidance Notes for Listing Class B/C/D In Vitro	P1	Existing wizard content update	Compare	High
SB-2026-122	Brazil	6/12/2026	ANVISA Expands Support and Improvement Measures to Supp	P1	Instructions/reference update	Compare	High
SB-2026-123	Kyrgyzstan	6/8/2026	On Amendments to the Resolution of the Cabinet of Minis	P1	Existing wizard content update	Compare	Medium
SB-2026-125	Mexico	6/17/2026	Cofepris has published an update to the Guide to Requir	P1	Existing wizard content update	Compare	High
SB-2026-127	Canada	6/17/2026	Phase 2 of our Work to Modernize Medical Device Establi	P1	Existing wizard content update	Compare	High
SB-2026-129	Belarus	6/16/2026	Transfer of Medical Device Regulatory Functions in Bela	P1	Existing wizard content update	Implement	High
SB-2026-130	Switzerland	6/18/2026	Swissdamed User Manual Actors	P1	Existing wizard content update	Implement	High
SB-2026-131	Rwanda	6/18/2026	Regulations Governing Good Manufacturing Practices of M	P1	Existing wizard content update	Compare	Medium
SB-2026-132	Botswana	6/18/2026	BOMRA Medical Devices, including IVDs, Regulatory Updat	P1	New wizard or coverage-gap ass	Monitor	Medium
SB-2026-133	Switzerland	6/19/2026	New Options for Product Registration in Swissdamed: Onl	P1	Instructions/reference update	Compare	Medium
SB-2026-137	Switzerland	6/19/2026	User Manual Swissdamed UDI Device Module	P1	Existing wizard content update	Compare	High
SB-2026-140	European Union	6/18/2026	MDCG Position Paper: Management of SS(C)P in EUDAMED af	P1	Instructions/reference update	Compare	Medium
SB-2026-142	Mexico	6/22/2026	Update on the Reliance Regulatory Fast Track Platform	P1	Conditional logic or pathway u	Compare	Medium
SB-2026-143	Korea	6/23/2026	Enforcement Decree of the Medical Device Act	P1	Existing wizard content update	Compare	High
SB-2026-146	Australia	6/24/2026	Complying with the Unique Device Identification timefra	P1	Instructions/reference update	Compare	Medium

SB-2026-147	Australia	6/24/2026	Unique Device Identification Consent to Supply process	P1	Conditional logic or pathway u	Compare	High
SB-2026-151	Kazakhstan	6/24/2026	Law of Kazakhstan On Amendments and Supplements to Cer	P1	Existing wizard content update	Compare	High
SB-2026-152	South Africa	6/25/2026	Communication on Research Use Only (RUO) and Investigat	P1	Official form/source-template	Implement	High
SB-2026-154	China	6/23/2026	China's NMPA Issues 2026 Revised Registration Review Gu	P1	Existing wizard content update	Compare	High
SB-2026-155	China	6/18/2026	China's NMPA Releases Technical Review Guidelines for V	P1	Existing wizard content update	Compare	Medium
SB-2026-156	China	6/15/2026	China's NMPA Issues Trial Technical Review Guidelines f	P1	Existing wizard content update	Compare	Medium
SB-2026-157	India	6/24/2026	Sale of In-Vitro Fertilization Media, Reagents, and Rel	P1	Existing wizard content update	Compare	Medium
SB-2026-158	Korea	6/23/2026	Enforcement Decree of the Medical Device Act	P1	Existing wizard content update	Compare	High
SB-2026-160	Brazil	6/25/2026	TECHNICAL NOTE Nº 41/2026/SEI/GQUIP/GGTPS/DIRE3/ANVISA	P1	Existing wizard content update	Compare	Medium
SB-2026-161	Korea	6/26/2026	Approval and Review Guideline for Digital Medical Devic	P1	Conditional logic or pathway u	Compare	High
SB-2026-162	Kyrgyzstan	6/18/2026	On Amendments to the Resolution of the Government of th	P1	Existing wizard content update	Compare	Medium
SB-2026-163	Oman	6/28/2026	Extension of Registration Period for High-Risk Medical	P1	Instructions/reference update	Compare	Medium
SB-2026-164	Malaysia	6/1/2026	Malaysia MDA: Fully Online Product Classification Appli	P1	Conditional logic or pathway u	Implement	High
SB-2026-003	Mexico	5/4/2026	Cofepris has published the "Agreement establishing meas	P2	Manual technical review	Escalate	Low
SB-2026-004	Mexico	5/4/2026	Cofepris has published the "Agreement Updating the Meth	P2	Manual technical review	Escalate	Low
SB-2026-005	Iraq	5/6/2026	Circular to Scientific Offices and Companies	P2	Instructions/reference update	Compare	Low
SB-2026-012	Chile	5/7/2026	Exempt Resolution No. 2.050/2026 approves the "Guidelin	P2	Manual technical review	Escalate	Low
SB-2026-013	Chile	5/6/2026	ISP Announces New Certification Program for Domestic an	P2	New wizard or coverage-gap ass	Monitor	Medium
SB-2026-015	United States	5/6/2026	Patient-Matched Guides for Orthopedic Implants	P2	Existing wizard content update	Compare	Medium
SB-2026-018	Switzerland	5/1/2026	Manufacturer Incident Report Guideline	P2	Existing wizard content update	Compare	Medium
SB-2026-019	Switzerland	5/1/2026	Information Sheet Combined Studies	P2	Instructions/reference update	Compare	Low
SB-2026-025	Algeria	5/10/2026	Note No. 41 to Pharmaceutical Establishment and Economi	P2	Instructions/reference update	Compare	Low
SB-2026-027	Hong Kong	5/13/2026	GN-00: Definitions and Abbreviations for the Medical De	P2	Instructions/reference update	Compare	Low
SB-2026-029	Turkey	5/13/2026	Guidelines for Registration Processes of Medical Device	P2	Manual technical review	Escalate	Low
SB-2026-031	Paraguay	5/13/2026	DINAVISA has published Resolution No. 189/2026	P2	Existing wizard content update	Compare	Low
SB-2026-032	United Kingdom	5/11/2026	MHRA invites Views on Proposed Changes to Medical Devic	P2	Watchlist—draft or unverified	Monitor	Medium
SB-2026-034	Finland	5/11/2026	Medical Device Manufacturers must report Serious Incide	P2	Manual technical review	Escalate	Low
SB-2026-036	Australia	5/12/2026	Preparing for an application audit for in-vitro diagnos	P2	Instructions/reference update	Compare	Medium
SB-2026-040	Peru	5/15/2026	DIGEMID - Announcement No. 006/2026	P2	Instructions/reference update	Compare	Low

SB-2026-044	China	5/8/2026	China NMPA Issues Guidance on Registration Review for P	P2	Existing wizard content update	Compare	Medium
SB-2026-045	Ireland	5/13/2026	Guide to Pre-submission Scientific and Regulatory Advic	P2	Instructions/reference update	Compare	Low
SB-2026-059	Mexico	5/21/2026	Guidelines for promoting National Investment in the pro	P2	Manual technical review	Escalate	Low
SB-2026-061	Kazakhstan	5/19/2026	Order of the Minister of Health of the Republic of Kaza	P2	Manual technical review	Escalate	Low
SB-2026-063	Australia	5/12/2026	Preparing for an application audit for in-vitro diagnos	P2	Instructions/reference update	Compare	Medium
SB-2026-068	Korea	5/26/2026	Approval and Review Procedures for New Technology Medic	P2	Existing wizard content update	Compare	Medium
SB-2026-069	Switzerland	5/26/2026	Template Trend Report	P2	Official form/source-template	Compare	Medium
SB-2026-070	Switzerland	5/26/2026	Template PSR Report	P2	Official form/source-template	Compare	Medium
SB-2026-071	South Africa	5/26/2026	Guideline on How to Respond to a GMP, GWP, GCP or GVP I	P2	Instructions/reference update	Compare	Medium
SB-2026-072	Korea	5/28/2026	FAQs for Medical Device Non-clinical Trials Guidance	P2	Instructions/reference update	Compare	Medium
SB-2026-075	Denmark	5/28/2026	Registration	P2	Manual technical review	Escalate	Low
SB-2026-078	Cameroon	5/29/2026	Implementation of a combined Individual Case Safety Rep	P2	Manual technical review	Escalate	Low
SB-2026-079	Iraq	5/31/2026	Announcement from the Pharmacy Department, Private Sect	P2	Instructions/reference update	Monitor	Low
SB-2026-080	Singapore	5/28/2026	How Medical Devices are Regulated by HSA and their Safe	P2	Instructions/reference update	Monitor	Low
SB-2026-085	Argentina	6/1/2026	Update on fees for ANMAT procedures	P2	Manual technical review	Escalate	Low
SB-2026-088	Syria	6/3/2026	Regulatory Decision 8/T	P2	Watchlist—draft or unverified	Escalate	Low
SB-2026-090	Iraq	6/3/2026	Circular No. 9/2/1163 To All Scientific Offices and Nat	P2	Instructions/reference update	Monitor	Low
SB-2026-093	Uzbekistan	5/5/2026	On measures to provide additional support to the privat	P2	Watchlist—draft or unverified	Monitor	Low
SB-2026-096	Uzbekistan	5/25/2026	Departmental regulatory legal act on the procedure for	P2	Instructions/reference update	Compare	Low
SB-2026-099	United States	6/5/2026	Intent to Exempt Certain Unclassified Medical Devices f	P2	Conditional logic or pathway u	Monitor	Medium
SB-2026-106	Switzerland	6/8/2026	Swissdamed Machine-to-Machine REST API Technical Docume	P2	Export/XML/data-mapping update	Monitor	Medium
SB-2026-124	China	6/5/2026	China's NMPA Announces Removal of 10 Medical Device Ind	P2	Manual technical review	Escalate	Low
SB-2026-126	Peru	6/17/2026	Announcement No. 008/2026 - Webinar on the Medical Devi	P2	Instructions/reference update	Monitor	Low
SB-2026-128	Saudi Arabia	6/18/2026	Standard Specification Annex No. (1) of the Technical R	P2	Watchlist—draft or unverified	Monitor	Medium
SB-2026-134	Switzerland	6/19/2026	Amendment to the Swissmedic Fee Ordinance as of July 1,	P2	Instructions/reference update	Compare	Medium
SB-2026-135	Switzerland	6/19/2026	Procurement of Medical Devices in Healthcare Facilities	P2	Manual technical review	Escalate	Low
SB-2026-136	Switzerland	6/19/2026	Swissdamed User Guide - Playground	P2	Instructions/reference update	Monitor	Low
SB-2026-138	Sweden	6/17/2026	The Swedish Medicines Agency will be responsible for AI	P2	Watchlist—draft or unverified	Monitor	Medium
SB-2026-139	European Union	6/17/2026	Guidance on standardisation for medical devices	P2	Instructions/reference update	Monitor	Medium

SB-2026-141	Bahrain	6/9/2026	Updated Fee Schedules of Services and Requests for Medi	P2	Instructions/reference update	Compare	Low
SB-2026-144	Australia	6/22/2026	New UDI Newsletter	P2	Instructions/reference update	Monitor	Low
SB-2026-145	Australia	6/22/2026	Getting started with UDI	P2	Instructions/reference update	Compare	Low
SB-2026-159	Bolivia	6/25/2026	CIRCULAR-22-2026	P2	Manual technical review	Escalate	Low
SB-2026-006	China	5/6/2026	NMPA Seeks Public Comments on Three Medical Device Regi	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-054	Kazakhstan	5/19/2026	Resolution of the Government of the Republic of Kazakhs	Watchlist	Watchlist—draft or unverified	Monitor	Low
SB-2026-055	Kazakhstan	5/19/2026	On Amendments to the Order of the Minister of Health of	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-056	China	5/12/2026	China Seeks Public Comment on Draft Registration Review	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-057	China	5/11/2026	China Seeks Public Comment on Draft Registration Review	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-058	China	5/6/2026	China Releases Draft Guidance for Public Comment on Thr	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-064	Kazakhstan	5/22/2026	On amendments and additions to the joint order of the M	Watchlist	Watchlist—draft or unverified	Monitor	Low
SB-2026-103	Nicaragua	6/8/2026	Public Consultation 175 - (NTON) 24001	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-110	China	6/3/2026	China NMPA Seeks Public Input on Four Draft Medical Dev	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-111	China	6/10/2026	China NMPA Opens Public Consultation on Draft Registrat	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-114	Kazakhstan	6/10/2026	On amendments to the order of the Minister of Health of	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-119	Korea	6/12/2026	Medical Device Manufacturing and Quality Control Standa	Watchlist	Watchlist—draft or unverified	Monitor	Medium
SB-2026-148	Brazil	6/23/2026	ANVISA Opens Public Call for Proposals to Improve Techn	Watchlist	Watchlist—draft or unverified	Monitor	Low
SB-2026-150	Kyrgyzstan	6/25/2026	Government's Decree	Watchlist	Watchlist—draft or unverified	Monitor	Low
SB-2026-153	China	6/17/2026	China's NMPA Invites Industry Participation in Drafting	Watchlist	Watchlist—draft or unverified	Monitor	Low
SB-2026-104	Lebanon	6/9/2026	Circular No. 22 Regarding the Entry of Import Invoices	No SB action	No SB impact	Close	High
SB-2026-113	Singapore	6/11/2026	Mean Applicant Screening Response Time Audiences	No SB action	No SB impact	Close	High
SB-2026-149	Denmark	6/18/2026	Fees for Clinical Trials of Medical Devices	No SB action	No SB impact	Close	High

Alert Detail — Page 4

In-Scope MD/IVD/Combination Device Alerts

Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-073 P0 Spain · 5/27/2026 · NotificationLaunch of RECOPS, the New Application for the Marketing Registration of Medical Devices	
Regulated-party impact	AEMPS launched RECOPS for marketing registration of MD and IVDs in Spain from May 27, 2026. Custom-made devices continue via RPS.
SB impact	Spain MD/IVD marketing registration wizard must be updated for RECOPS portal fields, attachments, identifiers, and applicant information. Separate custom-made device pathway (RPS) must be maintained. This is a P0 release blocker — any Spain wizard is materially incorrect if it does not reference RECOPS.
Impact category	Conditional logic or pathway update + Existing wizard content update
Affected pathway	New registration
Affected elements	RECOPS fields, Spain wizard submission channel, MD/IVD registration pathway, custom-made device RPS exception, applicant information, labeling/IFU attachments, device identifiers
Required action	Implement
Enforcement date	6/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.aemps.gob.es/informa/puesta-en-marcha-de-recops-...
SB-2026-081 P0 United States · 5/28/2026 · GuidanceContent of Human Factors Information in Medical Device Marketing Submissions	
Regulated-party impact	FDA guidance on Human Factors content in marketing submissions effective Aug 1, 2026. Manufacturers must include HF summaries in 510(k)/PMA/De Novo.
SB impact	eSTAR wizard (IVD and nIVD) must incorporate new HF submission content requirements. This is the companion guidance to the eSTAR program update.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	HF summary section, formative/summative study fields, use error analysis, IFU/labeling usability questions
Required action	Implement
Enforcement date	5/29/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.fda.gov/media/163694/download
SB-2026-086 P0 United States · 6/1/2026 · GuidanceeSTAR Program	
Regulated-party impact	FDA updated eSTAR IVD and nIVD source files effective August 1, 2026, incorporating Human Factors guidance content.
SB impact	eSTAR IVD and nIVD wizards must be updated: new HF question content, conditional logic, PDF/XML source file associations, and export parity testing required before Aug 1.
Impact category	Existing wizard content update + Export/XML/data-mapping update
Affected pathway	New registration
Affected elements	IVD eSTAR source file, nIVD eSTAR source file, HF question blocks, conditional logic, XML label mapping, PDF output, export testing
Required action	Implement
Enforcement date	8/1/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.fda.gov/medical-devices/how-study-and-market-you...
SB-2026-001 P1 Malaysia · 5/1/2026 · NotificationJoint Announcement by Medical Device Authority (MDA) Malaysia and Thai Food and Drug Admin	
Regulated-party impact	Malaysia MDA and Thailand FDA joint announcement on device regulatory cooperation.
SB impact	Monitor for reliance pathway implications. If Malaysia accepts Thai FDA approvals via reliance, wizard pathway logic may need updating.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Reliance pathway, submission type selection
Required action	Monitor
Enforcement date	5/1/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://portal.mda.gov.my/index.php/ms/pengumuman/1795-joint...

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Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-002

P1

Turkey · 5/4/2026 · Announcement

Mandatory Use of the EUDAMED Database System (Law No. 2026/KKB-1) and its Impact on the ÜT

Regulated-party impact	EUDAMED-related notification.
SB impact	Review wizard references to EUDAMED and ensure actor/UDI registration guidance is current.
Impact category	Instructions/reference update
Affected pathway	UDI / New registration
Affected elements	EUDAMED references, actor registration
Required action	Compare
Enforcement date	5/4/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.titck.gov.tr/duyuru/2026-kkb-1-sayili-eudamed-ve...

SB-2026-007

P1

Australia · 5/4/2026 · Guidance

Accessing and using the AusUDID

Regulated-party impact	TGA updated guidance on accessing and using the Australian UDI Database (AusUDID).
SB impact	Australia UDI wizard sections must reflect current AusUDID access and submission methods.
Impact category	Existing wizard content update
Affected pathway	UDI
Affected elements	AusUDID access guidance, UDI submission fields
Required action	Compare
Enforcement date	N/A
Confidence · Validation	High · Pending human validation
Official source	https://www.tga.gov.au/products/medical-devices/labelling-an...

SB-2026-008

P1

Australia · 5/4/2026 · Guidance

AusUDID submission methods

Regulated-party impact	TGA published AusUDID submission methods guidance.
SB impact	Australia UDI wizard submission method options should reflect AusUDID submission methods.
Impact category	Existing wizard content update
Affected pathway	UDI
Affected elements	UDI submission method selection, AusUDID fields
Required action	Compare
Enforcement date	N/A
Confidence · Validation	High · Pending human validation
Official source	https://www.tga.gov.au/products/medical-devices/labelling-an...

SB-2026-009

P1

Australia · 5/4/2026 · Guidance

Accessing the AusUDID

Regulated-party impact	TGA guidance on accessing AusUDID.
SB impact	Update Australia UDI wizard help text and instructions.
Impact category	Instructions/reference update
Affected pathway	UDI
Affected elements	UDI wizard instructions
Required action	Compare
Enforcement date	N/A
Confidence · Validation	Medium · Pending human validation
Official source	https://www.tga.gov.au/resources/resources/user-guide/access...

SB-2026-010

P1

Australia · 5/4/2026 · Guidance

AusUDID data elements

Regulated-party impact	TGA published AusUDID data elements guidance.
SB impact	Australia UDI wizard data fields must align with AusUDID data elements.
Impact category	Existing wizard content update
Affected pathway	UDI
Affected elements	UDI data fields, data element mapping
Required action	Compare
Enforcement date	N/A
Confidence · Validation	High · Pending human validation
Official source	https://www.tga.gov.au/products/medical-devices/labelling-an...

SB-2026-011

P1

Saudi Arabia · 5/5/2026 · Guidance

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

Regulated-party impact	SFDA published bundling criteria for devices within a single MDMA application.
SB impact	Saudi Arabia bundling/grouping wizard logic must reflect new SFDA bundling criteria.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Bundling criteria, grouping logic, MDMA application wizard
Required action	Compare
Enforcement date	5/5/2026
Confidence · Validation	High · Pending human validation
Official source	https://sfda.gov.sa/en/taxonomy/term/3

SB-2026-014

P1

Spain · 5/4/2026 · Notification

The AEMPS Updates the Information on the Medical Device Surveillance System and the Functi

Regulated-party impact	Spain AEMPS updated surveillance system information linked to RECOPS launch.
SB impact	Confirm Spain post-market and registration wizard references are current with RECOPS launch.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Submission instructions, post-market references
Required action	Compare
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://www.aemps.gob.es/informa/la-aemps-actualiza-la-infor...

SB-2026-016

P1

European Union · 5/5/2026 · Guidance

Implementing Regulation (EU) 2026/977 – Uniform Requirements for Conformity Assessment and

Regulated-party impact	EU published uniform requirements for conformity assessment procedures (MDR/IVDR). Economic operators must comply.
SB impact	Verify EU MDR/IVDR conformity assessment wizard sections align with 2026/977 requirements. Check QMS and technical file section references.
Impact category	Existing wizard content update
Affected pathway	New registration / Renewal
Affected elements	Conformity assessment section, QMS evidence fields, notified body references, Annex references
Required action	Compare
Enforcement date	5/4/2026
Confidence · Validation	High · Pending human validation
Official source	https://eur-lex.europa.eu/eli/reg_impl/2026/977/oj

SB-2026-017

P1

Denmark · 5/5/2026 · Notification

Medical Devices with Incorporated Drug

Regulated-party impact	Denmark DKMA notification on combination products (medical devices with incorporated drug).
SB impact	Denmark wizard combination product pathway should reflect current requirements for devices with incorporated drugs.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Combination product pathway, drug-device wizard, Denmark
Required action	Compare
Enforcement date	—
Confidence · Validation	High · Pending human validation
Official source	https://laegemiddelstyrelsen.dk/da/udstyr/bemyndigede-organe...

SB-2026-020

P1

Saudi Arabia · 5/5/2026 · Forms

SFDA Medical Devices Forms Updates

Regulated-party impact	Saudi Arabia SFDA updated medical device forms.
SB impact	Saudi Arabia wizard source forms must be updated to reflect new SFDA form versions.
Impact category	Official form/source-template update
Affected pathway	New registration
Affected elements	Application forms, form fields, Saudi Arabia wizard source templates
Required action	Implement
Enforcement date	5/5/2026
Confidence · Validation	High · Pending human validation
Official source	https://sfda.gov.sa/en/forms?keys=&date%5Bmin%5D=&date%5Bmax...

SB-2026-021

P1

Turkey · 5/7/2026 · Announcement

TCOKKA - Publication of Implementing Regulation (EU) 2026/977 on Common Requirements for N

Regulated-party impact	EU published uniform requirements for conformity assessment procedures (MDR/IVDR). Economic operators must comply.
SB impact	Verify EU MDR/IVDR conformity assessment wizard sections align with 2026/977 requirements. Check QMS and technical file section references.
Impact category	Existing wizard content update
Affected pathway	New registration / Renewal
Affected elements	Conformity assessment section, QMS evidence fields, notified body references, Annex references
Required action	Compare
Enforcement date	Not Announced
Confidence · Validation	High · Pending human validation
Official source	https://www.titck.gov.tr/duyuru/tcokka-avrupa-komisyonunca-o...

SB-2026-022

P1

Australia · 5/11/2026 · Guidance

Using assessments from comparable overseas regulators for medical devices

Regulated-party impact	TGA updated guidance on using comparable overseas regulator assessments for device registration.
SB impact	Australia reliance/abridged pathway wizard logic should reflect updated comparable overseas regulator guidance.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Reliance pathway wizard, comparable regulator list, supporting evidence fields
Required action	Compare
Enforcement date	N/A
Confidence · Validation	High · Pending human validation
Official source	https://www.tga.gov.au/resources/guidance/using-assessments-...

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Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-023 P1 Australia · 5/11/2026 · Guidance **Use of market authorisation evidence from comparable overseas regulators and assessment bo**

Regulated-party impact	TGA guidance on using overseas market authorization evidence.
SB impact	Australia reliance pathway wizard evidence requirements should be reviewed.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Reliance evidence fields, overseas authorization references
Required action	Compare
Enforcement date	N/A
Confidence · Validation	High · Pending human validation
Official source	https://www.tga.gov.au/resources/guidance/use-market-authori...

SB-2026-024 P1 Switzerland · 5/10/2026 · Guidance **Swissdamed User Manual Actors**

Regulated-party impact	Switzerland mandatory Swissdamed use from July 1, 2026. Actors must register in Swissdamed.
SB impact	Switzerland wizard must cover Swissdamed actor registration pathway. Separate assessments needed for: MD, IVD, SPP, legacy devices, transitional registrations, immediate registration exception (serious incidents/FSCA), per-UDI-DI fees.
Impact category	Existing wizard content update
Affected pathway	New registration / Actor registration
Affected elements	Actor registration, SRN equivalent, MD registration pathway, IVD pathway, SPP pathway, legacy device pathway, transitional rules, immediate registration trigger, fee fields
Required action	Implement
Enforcement date	5/10/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

SB-2026-026 P1 Algeria · 5/11/2026 · Notice **Note No. 42 to Pharmaceutical Establishment Relating to Requests for Classification of Pro**

Regulated-party impact	Algeria note on classification requests for economic operators.
SB impact	Algeria MD classification wizard may need update.
Impact category	Existing wizard content update
Affected pathway	Classification
Affected elements	Classification wizard, Algeria
Required action	Compare
Enforcement date	5/11/2026
Confidence · Validation	Low · Pending human validation
Official source	https://drive.google.com/file/d/18bQPujwVZSPdJOU3HPKIs8mp5O...

SB-2026-028 P1 Egypt · 5/14/2026 · Guideline **Regulatory Guideline on Requirements for Unique Device Identification (UDI) for Medical De**

Regulated-party impact	Egypt published UDI regulatory guideline for medical devices.
SB impact	Egypt UDI wizard section must be reviewed against new guideline requirements.
Impact category	Existing wizard content update
Affected pathway	UDI
Affected elements	UDI data fields, GTIN, UDI-DI, UDI-PI, Egypt UDI wizard
Required action	Compare
Enforcement date	5/14/2026
Confidence · Validation	High · Pending human validation
Official source	https://edaegypt.gov.eg/media/g1cjd3z/5-udi_up-2026.pdf

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Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-030 P1 Nicaragua · 5/13/2026 · Regulation **New Importation/Exportation Form**

Regulated-party impact	Nicaragua updated importation/exportation form for medical devices.
SB impact	Nicaragua import authorization wizard source form must be updated.
Impact category	Official form/source-template update
Affected pathway	Import authorization
Affected elements	Import form, form fields, Nicaragua wizard
Required action	Implement
Enforcement date	5/13/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.minsa.gob.ni/sites/default/files/publicaciones/F...

SB-2026-033 P1 United Kingdom · 5/13/2026 · Guidance **Medical Devices: Conformity Assessment and the UKCA Mark**

Regulated-party impact	MHRA updated conformity assessment and UKCA guidance.
SB impact	UK MD/IVD wizard conformity assessment and UKCA sections should be reviewed.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	UKCA pathway, conformity assessment fields, NB references
Required action	Compare
Enforcement date	5/13/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.gov.uk/guidance/medical-devices-conformity-asses...

SB-2026-035 P1 Bahrain · 5/13/2026 · Circular **Launch of TATABU Medical Devices & Supplies Traceability System**

Regulated-party impact	Bahrain NHRA launched TATABU traceability system for medical devices.
SB impact	Assess whether Bahrain wizard covers TATABU registration/traceability requirements.
Impact category	New wizard or coverage-gap assessment
Affected pathway	New registration
Affected elements	Bahrain traceability system, device registration fields
Required action	Monitor
Enforcement date	5/13/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.nhra.bh/MediaHandler/GenericHandler/documents/de...

SB-2026-037 P1 Malaysia · 5/15/2026 · Guidance **Requirements for Labelling of Medical Devices**

Regulated-party impact	Malaysia MDA published updated labeling requirements for medical devices.
SB impact	Malaysia MD registration wizard labeling section must be reviewed against new MDA requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Labeling fields, IFU requirements, language requirements, MDA labeling checklist
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://portal.mda.gov.my/index.php/ms/pengumuman/1800-revis...

SB-2026-038 P1 Malaysia · 5/15/2026 · Guidance **Change Management for Registered Medical Devices**

Regulated-party impact	Malaysia MDA published change management guidance for registered devices.
SB impact	Malaysia variation/change notification wizard must be reviewed against new change management guidance.
Impact category	Existing wizard content update
Affected pathway	Variation
Affected elements	Variation wizard, change notification fields, change categories, supporting documents
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://portal.mda.gov.my/index.php/ms/pengumuman/1799-publi...

SB-2026-039 P1 Ecuador · 5/18/2026 · Resolution **ARCSA has published Resolution ARCSA-DE-2026-003-DASP - Technical Health Regulations for O**

Regulated-party impact	Ecuador ARCSA published technical health regulation for medical device storage, distribution, and transport (GDP/GMP).
SB impact	Ecuador wizard GMP/GDP evidence requirements should reflect new ARCSA resolution.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	GMP/GDP evidence, distribution requirements, technical file sections
Required action	Compare
Enforcement date	1/28/2027
Confidence · Validation	Medium · Pending human validation
Official source	https://esacc.corteconstitucional.gob.ec/storage/api/v1/10_D...

SB-2026-041 P1 Nicaragua · 5/15/2026 · Guidance **User Guide for Requesting the Issuance of a Registration Certificate and Related Procedure**

Regulated-party impact	Nicaragua published updated user guide for registration certificate requests.
SB impact	Nicaragua wizard submission instructions should reference updated user guide.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Submission instructions, registration certificate fields
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.minsa.gob.ni/sites/default/files/publicaciones/M...

SB-2026-042 P1 Nicaragua · 5/15/2026 · Guidance **New Official Request Form for Health Registration Certificates and Signature Validation of**

Regulated-party impact	Nicaragua new official request form for health registration certificates.
SB impact	Nicaragua wizard source form for registration certificates must be updated.
Impact category	Official form/source-template update
Affected pathway	New registration
Affected elements	Registration form, form fields
Required action	Implement
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.minsa.gob.ni/sites/default/files/publicaciones/F...

SB-2026-043 **P1** Vietnam · 5/15/2026 · Notification **Notice on Domain Change for the Online Public Service Portal of Vietnam Infrastructure and**

Regulated-party impact	Vietnam changed domain for online public service portal.
SB impact	Vietnam wizard submission channel URL/link must be updated.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Submission URL, portal link, Vietnam wizard
Required action	Implement
Enforcement date	10/1/2026
Confidence · Validation	High · Pending human validation
Official source	https://imda.moh.gov.vn/trangchu

SB-2026-046 **P1** United Kingdom · 5/14/2026 · Guidance **Clinical Investigations for Medical Devices**

Regulated-party impact	MHRA updated clinical investigation submission guidance including IRAS integration and supporting document requirements.
SB impact	UK clinical investigation wizard must be updated to reflect IRAS requirements and new supporting document checklist.
Impact category	Existing wizard content update
Affected pathway	Clinical investigation
Affected elements	IRAS integration, supporting documents, clinical investigation application wizard
Required action	Compare
Enforcement date	5/14/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.gov.uk/guidance/notify-mhra-about-a-clinical-inv...

SB-2026-047 **P1** Serbia · 5/15/2026 · Guidance **New Conditions and Methods of Recognition of Foreign Documents of Conformity (Declaration**

Regulated-party impact	Serbia updated conditions for recognition of foreign conformity documents for devices.
SB impact	Serbia reliance/recognition wizard pathway must reflect new recognition conditions.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Recognition pathway, foreign conformity document fields, Serbia wizard
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.alims.gov.rs/wp-content/uploads/2026/05/1a.NOVI-...

SB-2026-048 **P1** Serbia · 5/15/2026 · Guidance **New Conditions and Methods of Recognition of Foreign Certificates of Conformity of Medical**

Regulated-party impact	Serbia updated conditions for recognition of foreign conformity certificates for IVDs.
SB impact	Serbia IVD recognition wizard pathway must reflect new conditions.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	IVD recognition pathway, certificate fields, Serbia IVD wizard
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.alims.gov.rs/wp-content/uploads/2026/05/1b.NOVI-...

SB-2026-049 P1 Serbia · 5/15/2026 · Guidance **New Conditions and Methods of Recognition of Foreign Documents of Conformity (Declaration**

Regulated-party impact	Serbia updated conditions for recognition of foreign conformity documents for devices.
SB impact	Serbia reliance/recognition wizard pathway must reflect new recognition conditions.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Recognition pathway, foreign conformity document fields, Serbia wizard
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.alims.gov.rs/wp-content/uploads/2026/05/2a.NOVI-...

SB-2026-050 P1 Serbia · 5/15/2026 · Guidance **New Conditions and Methods of Recognition of Foreign Certificates of Conformity (EC Certif**

Regulated-party impact	Serbia updated conditions for recognition of foreign conformity certificates for IVDs.
SB impact	Serbia IVD recognition wizard pathway must reflect new conditions.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	IVD recognition pathway, certificate fields, Serbia IVD wizard
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.alims.gov.rs/wp-content/uploads/2026/05/2b.NOVI-...

SB-2026-051 P1 Serbia · 5/15/2026 · Guidance **Instructions for Submitting a Request for Amendment/Additional Registration of a Medical D**

Regulated-party impact	Serbia published instructions for amendment/additional registration submissions.
SB impact	Serbia variation/amendment wizard should reflect new submission instructions.
Impact category	Existing wizard content update
Affected pathway	Variation
Affected elements	Amendment wizard, supporting document requirements
Required action	Compare
Enforcement date	5/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.alims.gov.rs/wp-content/uploads/2026/05/4d.-Uput...

SB-2026-052 P1 Czech Republic · 5/18/2026 · Notification **Application for Authorization to place a Medical Device on the Market in the Czech Republi**

Regulated-party impact	Czech Republic updated application procedure for placing MD on market.
SB impact	Czech Republic wizard should reflect updated authorization application requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Authorization application wizard, Czech Republic
Required action	Compare
Enforcement date	5/18/2026
Confidence · Validation	High · Pending human validation
Official source	https://sukl.gov.cz/pokyny-ustavu/pokyny-zdravotnicke-prostr...

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SB-2026-053 P1 Mexico · 5/19/2026 · Standard **Cofepris has published Mexican Official Standard NOM-137-SSA1-2025 - Labeling of Medical D**

Regulated-party impact	Mexico COFEPRIS published NOM-137-SSA1-2025 on labeling of medical devices.
SB impact	Mexico MD wizard labeling section must be updated to reflect NOM-137-SSA1-2025.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Labeling fields, NOM standard reference, Mexico wizard
Required action	Implement
Enforcement date	5/19/2027
Confidence · Validation	High · Pending human validation
Official source	https://diariooficial.gob.mx/nota_detalle.php?codigo=5787790...

SB-2026-060 P1 Peru · 5/21/2026 · Resolution **DIGEMID has published Ministerial Resolution No. 193-2026/MINSA**

Regulated-party impact	Peru DIGEMID published Ministerial Resolution 193-2026/MINSA (details to be confirmed from source).
SB impact	Review Peru wizard against Resolution 193-2026/MINSA.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Peru wizard, registration requirements
Required action	Compare
Enforcement date	5/21/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.digemid.minsa.gob.pe/webDigemid/normas-legales/2...

SB-2026-062 P1 Australia · 5/22/2026 · guidance **Complying with the Unique Device Identification timeframes for medical devices**

Regulated-party impact	TGA published/updated UDI compliance timeline guidance.
SB impact	Australia UDI wizard timeline references and compliance milestones should be current.
Impact category	Instructions/reference update
Affected pathway	UDI
Affected elements	UDI compliance timeline, deadline fields
Required action	Compare
Enforcement date	N/A
Confidence · Validation	Medium · Pending human validation
Official source	https://www.tga.gov.au/resources/guidance/complying-unique-d...

SB-2026-065 P1 Czech Republic · 5/18/2026 · Notification **Methodological Instructions for Submitting an Application for a Free Sale Certificate (FSC)**

Regulated-party impact	Czech Republic updated instructions for Free Sale Certificate applications.
SB impact	Czech Republic FSC wizard should reflect new methodological instructions.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	FSC wizard, supporting documents, Czech Republic
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	High · Pending human validation
Official source	https://sukl.gov.cz/pokyny-ustavu/pokyny-zdravotnicke-prostr...

SB-2026-066 P1 Sweden · 5/25/2026 · Guidance **Regulations (HSLF-FS 2026:11) amending the Medical Products Agency's regulations (HSLF-FS**

Regulated-party impact	Sweden MPA amending regulation for medical devices.
SB impact	Sweden wizard regulatory reference update required.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Regulatory references, Sweden MD wizard
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.lakemedelsverket.se/sv/lagar-och-regler/foreskri...

SB-2026-067 P1 Portugal · 5/20/2026 · Circular **Operationalization of EUDAMED on May 28, 2026**

Regulated-party impact	Portugal INFARMED circular on EUDAMED mandatory use from May 28.
SB impact	Portuguese market: Update submission instructions and references to EUDAMED in MDR/IVDR wizards. Confirm SRN/actor registration guidance is current.
Impact category	Instructions/reference update
Affected pathway	New registration / UDI
Affected elements	Submission instructions, EUDAMED references, wizard help text
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.infarmed.pt/documents/15786/12277909/Operacional...

SB-2026-074 P1 Denmark · 5/27/2026 · Notification **Distributor and Specialist Store Registration**

Regulated-party impact	Denmark DKMA notification on distributor and specialist store registration in EUDAMED.
SB impact	Denmark wizard for distributor/specialist store actor registration should reflect current EUDAMED requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Actor registration, distributor wizard, EUDAMED references, Denmark
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://laegemiddelstyrelsen.dk/da/udstyr/registrering/regis...

SB-2026-076 P1 Denmark · 5/28/2026 · Notification **Registration in Eudamed**

Regulated-party impact	EUDAMED-related notification.
SB impact	Review wizard references to EUDAMED and ensure actor/UDI registration guidance is current.
Impact category	Instructions/reference update
Affected pathway	UDI / New registration
Affected elements	EUDAMED references, actor registration
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://laegemiddelstyrelsen.dk/da/nyheder/senest-opdaterede...

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SB-2026-077 P1 Czech Republic · 5/27/2026 · Notification **Temporary Retention of FSC Applications through RZPRO**

Regulated-party impact	Czech Republic announced temporary retention of FSC applications through RZPRO system.
SB impact	Czech Republic FSC wizard submission channel references should reflect RZPRO retention.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	FSC submission channel, Czech Republic
Required action	Compare
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://sukl.gov.cz/zdravotnicke-prostredky/aktuality-zp/doc...

SB-2026-082 P1 Belgium · 5/28/2026 · Notification **EUDAMED: Clarifications Regarding Obligations as of 28 May 2026**

Regulated-party impact	EUDAMED mandatory from May 28, 2026. Manufacturers and economic operators must register actors and devices in EUDAMED.
SB impact	Manufacturer-facing: Actor registration and UDI/Device registration modules are directly in scope. Market Surveillance module = competent authorities. NB/Cert module = notified bodies. Verify MDR/IVDR device registration wizards reference EUDAMED actor/SRN requirements. Legacy device and SPP pathways need separate review.
Impact category	Existing wizard content update
Affected pathway	New registration / UDI
Affected elements	Actor registration (SRN), UDI/Device registration data fields, MDR wizard, IVDR wizard, legacy device pathway, SPP pathway
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.fagg.be/nl/news/eudamed_verduidelijkingen_over_d...

SB-2026-083 P1 Slovenia · 5/13/2026 · General informative document **Q&A Education May 13, 2026: Obligations of Distributors and Importers**

Regulated-party impact	Slovenia informational Q&A on distributor/importer obligations under MDR/IVDR.
SB impact	Slovenia wizard for distributors/importers should reflect obligations outlined in Q&A.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Distributor/importer obligations, economic operator wizard, Slovenia
Required action	Compare
Enforcement date	5/13/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.jazmp.si/medicinski-pripomocki/splosno-o-medicin...

SB-2026-084 P1 Brazil · 6/1/2026 · Guidance **Guidance: Importation via DUIMP_v1.9**

Regulated-party impact	ANVISA updated DUIMP importation guidance to v1.9.
SB impact	Brazil import authorization wizard instructions should reference DUIMP v1.9.
Impact category	Instructions/reference update
Affected pathway	Import authorization
Affected elements	Import instructions, DUIMP reference, Brazil wizard
Required action	Compare
Enforcement date	6/1/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.gov.br/anvisa/pt-br/centraisdeconteudo/publicaco...

SB-2026-087

P1

Czech Republic · 6/1/2026 · Guideline

Methodological Guideline for the Implementation of MDR Requirements for Custom-Made Device

Regulated-party impact	Czech Republic published MDR implementation guideline for custom-made devices.
SB impact	Czech Republic custom-made device wizard should reflect new MDR implementation guideline.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Custom-made device wizard, MDR requirements, Czech Republic
Required action	Compare
Enforcement date	6/1/2026
Confidence · Validation	High · Pending human validation
Official source	https://sukl.gov.cz/pokyny-ustavu/pokyny-zdravotnicke-prostr...

SB-2026-089

P1

Oman · 6/3/2026 · Regulation

Requirements for Approval of Optical Companies Applying for Medical Device Establishment

Regulated-party impact	Oman MoH published requirements for optical company approval for device registration.
SB impact	Oman wizard for optical device registrations should reflect new approval requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Optical device pathway, Oman wizard
Required action	Compare
Enforcement date	6/3/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://drive.google.com/file/d/1VCC6GcrOqo03Z-vEWDYfqiHGpef...

SB-2026-091

P1

Switzerland · 6/2/2026 · Guidance

Swissdamed Business Rules

Regulated-party impact	Swissdamed business rules published. Manufacturers must comply with data submission rules.
SB impact	Switzerland wizard data fields must align with Swissdamed business rules. Validate data dictionary mapping.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Data fields, business rules, validation logic
Required action	Compare
Enforcement date	6/2/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

SB-2026-092

P1

Uzbekistan · 5/27/2026 · General alert

New legislative changes will come into force in Uzbekistan on June 1

Regulated-party impact	Uzbekistan legislative changes effective June 1, 2026 affecting medical sector.
SB impact	Uzbekistan wizard should be reviewed against June 1 legislative changes.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Registration requirements, Uzbekistan wizard
Required action	Compare
Enforcement date	6/1/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.uzdaily.uz/ru/s-1-iiunia-v-uzbekistane-vstupaiut...

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SB-2026-094 P1 Singapore · 6/2/2026 · Guidance **GN-12-1: Guidance on Grouping of Medical Devices for Product Registration – General Group**

Regulated-party impact	Singapore HSA published grouping guidance for medical device registration.
SB impact	Singapore MD grouping/bundling logic in wizard should reflect GN-12-1.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Grouping logic, bundling criteria, Singapore wizard
Required action	Compare
Enforcement date	6/2/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.hsa.gov.sg/medical-devices/guidance-documents/#t...

SB-2026-095 P1 South Africa · 6/4/2026 · Guidance **Regulatory Requirements for Medical Devices Electronic Instructions for Use (e-IFU)**

Regulated-party impact	South Africa SAHPRA published eIFU regulatory requirements.
SB impact	South Africa MD wizard labeling/IFU section should include eIFU requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	IFU fields, eIFU eligibility, labeling wizard section
Required action	Compare
Enforcement date	6/4/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.sahpra.org.za/document/regulatory-requirements-f...

SB-2026-097 P1 Germany · 5/28/2026 · News **European Database for Medical Devices: EUDAMED**

Regulated-party impact	Germany BfArM/DIMDI EUDAMED mandatory use notification.
SB impact	German market: Update wizard references to EUDAMED. Confirm actor registration and UDI wizard sections are current.
Impact category	Instructions/reference update
Affected pathway	New registration / UDI
Affected elements	EUDAMED references, actor registration help text
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.bfarm.de/DE/Medizinprodukte/Ueberblick/Europa-un...

SB-2026-098 P1 Germany · 5/28/2026 · Notification **May 28, 2026: Initial and Amendment Notification MP and IVD**

Regulated-party impact	Germany updated initial and amendment notification procedures under MDR/IVDR as of May 28 (linked to EUDAMED mandatory use).
SB impact	German MDR/IVDR new registration and variation wizards should reflect updated notification process.
Impact category	Existing wizard content update
Affected pathway	New registration / Variation
Affected elements	Notification fields, EUDAMED references, variation/amendment wizard
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte...

SB-2026-100 P1 Sri Lanka · 5/21/2026 · Notification **Reissuance of Sample Import License (SIL)-Medical Devices**

Regulated-party impact	Sri Lanka updated Sample Import License process for medical devices.
SB impact	Sri Lanka SIL wizard or import authorization pathway should reflect reissuance process.
Impact category	Existing wizard content update
Affected pathway	Import authorization
Affected elements	SIL fields, import authorization wizard, Sri Lanka
Required action	Compare
Enforcement date	N/A
Confidence · Validation	Medium · Pending human validation
Official source	https://cdn.prod.website-files.com/666d0695ca3ba7fa496a5068/...

SB-2026-101 P1 Sri Lanka · 5/21/2026 · Notification **Checklist for Document Accepting of Consolidated new Medical Device applications**

Regulated-party impact	Sri Lanka published updated document checklist for new MD applications.
SB impact	Sri Lanka wizard supporting document requirements should reflect updated checklist.
Impact category	Official form/source-template update
Affected pathway	New registration
Affected elements	Supporting documents checklist, Sri Lanka wizard
Required action	Implement
Enforcement date	7/7/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.nmra.gov.lk/pages/medical-devices

SB-2026-102 P1 Algeria · 5/13/2026 · Guidance **Guidelines for Regulatory Trust (Reliance) and Recognition Practices in Good Manufacturing**

Regulated-party impact	Algeria published reliance and recognition guidelines.
SB impact	Algeria reliance pathway wizard should reflect new guidelines.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Reliance pathway, recognition criteria
Required action	Compare
Enforcement date	5/13/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://anpp.dz/fr/guidelines/

SB-2026-105 P1 Lebanon · 6/9/2026 · Circular **Circular No. 23 Regarding FDA-Approved Implantable Medical Devices**

Regulated-party impact	Lebanon circular on FDA-approved implantable devices import requirements.
SB impact	Lebanon implantable device import wizard may need to reference FDA approval status as a requirement.
Impact category	Existing wizard content update
Affected pathway	Import authorization
Affected elements	Import authorization, FDA approval evidence, implantable device fields, Lebanon wizard
Required action	Compare
Enforcement date	6/9/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.moph.gov.lb/files/laws/files/Tamim_23_2026.pdf

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SB-2026-107	P1	Germany · 6/9/2026 · News notification	Self-declaration Regarding the Implementation of the Requirements for Writing to the Elect
Regulated-party impact	Germany self-declaration requirement for writing-to-address (Schreibweise) under MDR/IVDR.		
SB impact	Germany MD/IVD wizard should incorporate self-declaration field for writing requirements.		
Impact category	Existing wizard content update		
Affected pathway	New registration		
Affected elements	Self-declaration field, Germany wizard		
Required action	Compare		
Enforcement date	6/5/2026		
Confidence · Validation	Medium · Pending human validation		
Official source	https://www.bfarm.de/SharedDocs/Downloads/DE/Medizinprodukte...		

SB-2026-108	P1	Latvia · 5/28/2026 · News notification	EUDAMED, The European Database for Medical Devices, Launches
Regulated-party impact	Latvia ZVAMC EUDAMED mandatory use announcement.		
SB impact	Latvian market wizard references to EUDAMED should be current.		
Impact category	Instructions/reference update		
Affected pathway	UDI / New registration		
Affected elements	Submission instructions		
Required action	Compare		
Enforcement date	5/28/2026		
Confidence · Validation	Low · Pending human validation		
Official source	https://www.zva.gov.lv/lv/jaunumi-un-publikacijas/jaunumi/da...		

SB-2026-109	P1	Luxembourg · 5/28/2026 · Medical Device news	Mandatory use of EUDAMED from May 28, 2026
Regulated-party impact	Luxembourg mandatory EUDAMED use from May 28, 2026.		
SB impact	Luxembourg wizard references and submission instructions should reflect mandatory EUDAMED use.		
Impact category	Instructions/reference update		
Affected pathway	UDI / New registration		
Affected elements	Submission instructions, wizard help text		
Required action	Compare		
Enforcement date	5/28/2026		
Confidence · Validation	Low · Pending human validation		
Official source	https://santesecu.public.lu/fr/espace-professionnel/departem...		

SB-2026-112	P1	China · 6/1/2026 · Notification	China NMPA Issues Announcement on Medical Device Classification Adjustment Procedures
Regulated-party impact	China NMPA announced classification adjustments for medical devices.		
SB impact	China wizard classification logic must reflect adjusted classifications.		
Impact category	Conditional logic or pathway update		
Affected pathway	Classification		
Affected elements	Classification wizard, device classification logic, China		
Required action	Compare		
Enforcement date	6/1/2026		
Confidence · Validation	High · Pending human validation		
Official source	https://www.nmpa.gov.cn/xxgk/ggtg/ylqxggtg/ylqxqtggtg/202606...		

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SB-2026-115 P1 Hungary · 6/10/2026 · Notification **Deviation from Conformity Assessment Procedures**

Regulated-party impact	Hungary OGYÉI notification on deviations from conformity assessment procedures.
SB impact	Hungary MD wizard conformity assessment section should note deviation procedure.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Conformity assessment, deviation pathway, Hungary wizard
Required action	Compare
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://ogyei.gov.hu/a_megfelelosegertekelési_eljarasoktol_v...

SB-2026-116 P1 Hungary · 6/10/2026 · Notification **Conformity Assessment Bodies**

Regulated-party impact	Hungary OGYÉI notification on conformity assessment bodies.
SB impact	Hungary wizard NB/conformity assessment body references may need updating.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	NB references, conformity assessment, Hungary wizard
Required action	Compare
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://ogyei.gov.hu/megfelelosegertekelo_szervezetek

SB-2026-117 P1 United Kingdom · 6/11/2026 · Guidance **Regulation of Medical Devices in Northern Ireland**

Regulated-party impact	MHRA updated Northern Ireland device regulation guidance.
SB impact	UK/Northern Ireland wizard pathway should reflect current MDR/IVDR NI rules.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Northern Ireland pathway, UKNI marking, Windsor Framework logic
Required action	Compare
Enforcement date	6/11/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.gov.uk/guidance/medical-devices-eu-regulations-f...

SB-2026-118 P1 Korea · 6/10/2026 · Guidance **Labeling Guideline for Digital Medical Devices**

Regulated-party impact	Korea MFDS published labeling guideline for digital medical devices (SaMD).
SB impact	Korea SaMD/digital device wizard labeling section must be reviewed.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Digital device labeling fields, SaMD wizard
Required action	Compare
Enforcement date	6/10/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.mfds.go.kr/brd/m_1060/view.do?seq=15870&srchFr=&...

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SB-2026-120 P1 Hong Kong · 6/12/2026 · Guidance **GN-02: Guidance Notes for Listing Class II/III/IV General Medical Devices**

Regulated-party impact	Hong Kong updated guidance for listing Class II/III/IV general medical devices.
SB impact	Hong Kong MD listing wizard must reflect updated GN-02 requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	MD listing wizard, Class II/III/IV fields, supporting documents
Required action	Compare
Enforcement date	6/12/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.mdd.gov.hk/tc/whats-new/mdacs-activities/index-i...

SB-2026-121 P1 Hong Kong · 6/12/2026 · Guidance **GN-06: Guidance Notes for Listing Class B/C/D In Vitro Diagnostic Medical Devices**

Regulated-party impact	Hong Kong updated guidance for listing Class B/C/D IVDs.
SB impact	Hong Kong IVD listing wizard must reflect updated GN-06 requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	IVD listing wizard, Class B/C/D fields, supporting documents
Required action	Compare
Enforcement date	6/12/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.mdd.gov.hk/tc/whats-new/mdacs-activities/index-i...

SB-2026-122 P1 Brazil · 6/12/2026 · Circular **ANVISA Expands Support and Improvement Measures to Support the Transition to the New Importation Process**

Regulated-party impact	ANVISA expanded support for SIUD/RDC 751 transition.
SB impact	Brazil UDI/SIUD wizard transition references should be updated.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	UDI transition, SIUD wizard, Brazil
Required action	Compare
Enforcement date	6/12/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/202...

SB-2026-123 P1 Kyrgyzstan · 6/8/2026 · Government's Decree **On Amendments to the Resolution of the Cabinet of Ministers of the Kyrgyz Republic “On App**

Regulated-party impact	Kyrgyzstan amended cabinet resolution on medical device registration.
SB impact	Kyrgyzstan wizard should be reviewed against amended resolution.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Registration requirements, Kyrgyzstan wizard
Required action	Compare
Enforcement date	6/18/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://cbd.minjust.gov.kg/7-55651/edition/54132/ru

SB-2026-125 P1 Mexico · 6/17/2026 · Guidance **Cofepris has published an update to the Guide to Requirements for the Sanitary Registratio**

Regulated-party impact	Mexico COFEPRIS updated requirements guide for sanitary registration of medical devices.
SB impact	Mexico MD registration wizard should be reviewed against updated COFEPRIS requirements guide.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Registration requirements, supporting documents, Mexico wizard
Required action	Compare
Enforcement date	6/17/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.gob.mx/cms/uploads/attachment/file/1084062/GUIA_...

SB-2026-127 P1 Canada · 6/17/2026 · Bulletin **Phase 2 of our Work to Modernize Medical Device Establishment Licensing**

Regulated-party impact	Health Canada Phase 2 of modernized Medical Device Establishment Licensing.
SB impact	Canada MDEL wizard should reflect Phase 2 modernization changes.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	MDEL wizard, establishment licensing fields, Canada
Required action	Compare
Enforcement date	12/14/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.canada.ca/en/health-canada/services/drugs-health...

SB-2026-129 P1 Belarus · 6/16/2026 · Notification **Transfer of Medical Device Regulatory Functions in Belarus**

Regulated-party impact	Belarus transferred MD regulatory functions to a new authority.
SB impact	Belarus wizard regulatory authority references and submission addresses must be updated.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Regulatory authority name, submission address, Belarus wizard
Required action	Implement
Enforcement date	6/30/2026
Confidence · Validation	High · Pending human validation
Official source	https://rceth.by/ru/News/1918

SB-2026-130 P1 Switzerland · 6/18/2026 · Guidance **Swissdamed User Manual Actors**

Regulated-party impact	Switzerland mandatory Swissdamed use from July 1, 2026. Actors must register in Swissdamed.
SB impact	Switzerland wizard must cover Swissdamed actor registration pathway. Separate assessments needed for: MD, IVD, SPP, legacy devices, transitional registrations, immediate registration exception (serious incidents/FSCA), per-UDI-DI fees.
Impact category	Existing wizard content update
Affected pathway	New registration / Actor registration
Affected elements	Actor registration, SRN equivalent, MD registration pathway, IVD pathway, SPP pathway, legacy device pathway, transitional rules, immediate registration trigger, fee fields
Required action	Implement
Enforcement date	6/15/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

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SB-2026-131 P1 Rwanda · 6/18/2026 · Regulation **Regulations Governing Good Manufacturing Practices of Medical Products**

Regulated-party impact	Rwanda published GMP regulations for medical products including devices.
SB impact	Rwanda wizard QMS/GMP evidence section should reflect new GMP regulations.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	GMP evidence, QMS section, Rwanda wizard
Required action	Compare
Enforcement date	6/18/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://rwandafda.gov.rw/monitoring-tool/documents-managemen...

SB-2026-132 P1 Botswana · 6/18/2026 · Announcement **BOMRA Medical Devices, including IVDs, Regulatory Update: Medical Device Regulatory Strate**

Regulated-party impact	Botswana BOMRA published regulatory update for MD and IVDs.
SB impact	Assess Botswana wizard coverage against BOMRA regulatory update.
Impact category	New wizard or coverage-gap assessment
Affected pathway	New registration
Affected elements	Botswana wizard coverage gap assessment
Required action	Monitor
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://www.bomra.co.bw/bomra-medical-devices-including-ivds...

SB-2026-133 P1 Switzerland · 6/19/2026 · Notification **New Options for Product Registration in Swissdamed: Online Editor and M2M Interface, and R**

Regulated-party impact	Swissdamed online editor and M2M interface available for product registration.
SB impact	Switzerland wizard submission instructions should reference online editor and M2M options.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Submission instructions, wizard help text
Required action	Compare
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://www.swissmedic.ch/swissmedic/de/home/medizinprodukte...

SB-2026-137 P1 Switzerland · 6/19/2026 · Guidance **User Manual Swissdamed UDI Device Module**

Regulated-party impact	Swissdamed UDI Device module user manual published. Manufacturers must submit UDI data in Swissdamed.
SB impact	Switzerland UDI wizard section must align with Swissdamed UDI Device module requirements and data fields.
Impact category	Existing wizard content update
Affected pathway	UDI
Affected elements	UDI data fields, UDI/Device module, Swissdamed UDI submission
Required action	Compare
Enforcement date	6/19/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

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SB-2026-140 **P1** European Union · 6/18/2026 · Guidance **MDCG Position Paper: Management of SS(C)P in EUDAMED after mandatory use**

Regulated-party impact	EUDAMED-related notification.
SB impact	Review wizard references to EUDAMED and ensure actor/UDI registration guidance is current.
Impact category	Instructions/reference update
Affected pathway	UDI / New registration
Affected elements	EUDAMED references, actor registration
Required action	Compare
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://health.ec.europa.eu/document/download/a80332cf-e9f0-...

SB-2026-142 **P1** Mexico · 6/22/2026 · Announcement **Update on the Reliance Regulatory Fast Track Platform**

Regulated-party impact	Mexico updated reliance regulatory fast track platform.
SB impact	Mexico reliance/fast track pathway wizard should reflect platform updates.
Impact category	Conditional logic or pathway update
Affected pathway	New registration
Affected elements	Reliance pathway, fast track selection, Mexico wizard
Required action	Compare
Enforcement date	6/19/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.gob.mx/cofepris/acciones-y-programas/via-regulat...

SB-2026-143 **P1** Korea · 6/23/2026 · Enforcement Decree **Enforcement Decree of the Medical Device Act**

Regulated-party impact	Korea Enforcement Decree of the Medical Device Act updated.
SB impact	Korea MD wizard pathway and eligibility logic should be reviewed against updated Enforcement Decree.
Impact category	Existing wizard content update
Affected pathway	New registration / Variation
Affected elements	Pathway eligibility, exemptions, classification, submission requirements
Required action	Compare
Enforcement date	7/1/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.law.go.kr/%EB%B2%95%EB%A0%B9/%EC%9D%98%EB%A3%8C%...

SB-2026-146 **P1** Australia · 6/24/2026 · Guidance **Complying with the Unique Device Identification timeframes for medical devices**

Regulated-party impact	TGA published/updated UDI compliance timeline guidance.
SB impact	Australia UDI wizard timeline references and compliance milestones should be current.
Impact category	Instructions/reference update
Affected pathway	UDI
Affected elements	UDI compliance timeline, deadline fields
Required action	Compare
Enforcement date	N/A
Confidence · Validation	Medium · Pending human validation
Official source	https://www.tga.gov.au/resources/guidance/complying-unique-d...

SB-2026-147 P1 Australia · 6/24/2026 · Notification **Unique Device Identification Consent to Supply process**

Regulated-party impact	TGA Consent to Supply (CTS) process updated in context of UDI requirements.
SB impact	Australia Consent to Supply pathway is separate from UDI pathway — should not be grouped under UDI wizard. Review CTS-specific fields and UDI linkage.
Impact category	Conditional logic or pathway update
Affected pathway	Import authorization
Affected elements	Consent to Supply pathway, CTS wizard, UDI linkage in CTS, import authorization fields
Required action	Compare
Enforcement date	N/A
Confidence · Validation	High · Pending human validation
Official source	https://www.tga.gov.au/products/medical-devices/labelling-an...

SB-2026-151 P1 Kazakhstan · 6/24/2026 · Law **Law of Kazakhstan On Amendments and Supplements to Certain Legislative Acts of the Republ**

Regulated-party impact	Kazakhstan enacted law amending legislative acts related to medical devices.
SB impact	Kazakhstan wizard should be reviewed against new law amendments.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Registration requirements, pathway, Kazakhstan wizard
Required action	Compare
Enforcement date	6/24/2026
Confidence · Validation	High · Pending human validation
Official source	https://continent-online.com/Document/?doc_id=35487579#pos=2...

SB-2026-152 P1 South Africa · 6/25/2026 · Guidance **Communication on Research Use Only (RUO) and Investigational Use Only (IUO) Medical Device**

Regulated-party impact	SAHPRA published communication on RUO/IUO devices and the GLF-MD-25A form update.
SB impact	South Africa RUO/IUO wizard or registration form must be updated to reflect GLF-MD-25A. This is a concrete form update, not just a communication.
Impact category	Official form/source-template update
Affected pathway	New registration
Affected elements	GLF-MD-25A form, RUO/IUO classification, South Africa wizard form fields
Required action	Implement
Enforcement date	6/25/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.sahpra.org.za/document/communication-on-research...

SB-2026-154 P1 China · 6/23/2026 · Guidance **China's NMPA Issues 2026 Revised Registration Review Guidelines for Medical MRI Systems**

Regulated-party impact	China NMPA revised registration review guidelines for MRI devices.
SB impact	China MRI device technical review section in wizard should reflect 2026 revised guidelines.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	MRI device technical requirements, China wizard
Required action	Compare
Enforcement date	6/23/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.cmde.org.cn/xwdt/shpgzg/gztg/20260623092501160....

SB-2026-155 P1 China · 6/18/2026 · Notification **China's NMPA Releases Technical Review Guidelines for Varicose Vein Closure Adhesive Devic**

Regulated-party impact	China NMPA issued technical review guidelines for varicose vein closure adhesives.
SB impact	China wizard for relevant product type should reference new guidelines.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Product-specific technical requirements, China wizard
Required action	Compare
Enforcement date	6/18/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/xwdt/shpgzgg/gztg/20260618145109105....

SB-2026-156 P1 China · 6/15/2026 · Notification **China's NMPA Issues Trial Technical Review Guidelines for Tumor Gene Variant Detection Rea**

Regulated-party impact	China NMPA issued trial technical review guidelines for tumor gene variant detection IVDs.
SB impact	China IVD wizard for oncology diagnostics should reference new guidelines.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	IVD technical requirements, oncology diagnostics section, China wizard
Required action	Compare
Enforcement date	6/15/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/xwdt/shpgzgg/gztg/20260615154311124....

SB-2026-157 P1 India · 6/24/2026 · Circular **Sale of In-Vitro Fertilization Media, Reagents, and Related Consumables Used Assisted Repr**

Regulated-party impact	India circular on sale of IVF media, reagents, and related consumables (IVD-related).
SB impact	India IVD wizard for IVF-related products should reflect regulatory requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	IVD wizard, IVF consumables, India
Required action	Compare
Enforcement date	6/24/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://cdsco.gov.in/opencms/opencms/system/modules/CDSCO.WE...

SB-2026-158 P1 Korea · 6/23/2026 · Guidance **Enforcement Decree of the Medical Device Act**

Regulated-party impact	Korea Enforcement Decree of the Medical Device Act updated.
SB impact	Korea MD wizard pathway and eligibility logic should be reviewed against updated Enforcement Decree.
Impact category	Existing wizard content update
Affected pathway	New registration / Variation
Affected elements	Pathway eligibility, exemptions, classification, submission requirements
Required action	Compare
Enforcement date	7/1/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.law.go.kr/%EB%B2%95%EB%A0%B9/%EC%9D%98%EB%A3%8C%...

SB-2026-160 P1 Brazil · 6/25/2026 · Regulation **TECHNICAL NOTE Nº 41/2026/SEI/GQUIP/GGTPS/DIRE3/ANVISA**

Regulated-party impact	ANVISA Technical Note 41/2026 on device registration (details to be confirmed).
SB impact	Review Brazil wizard against ANVISA Technical Note 41/2026.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Brazil wizard, registration requirements
Required action	Compare
Enforcement date	6/25/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.gov.br/anvisa/pt-br/setorregulado/regularizacao/...

SB-2026-161 P1 Korea · 6/26/2026 · Guidance **Approval and Review Guideline for Digital Medical Device Change Control Plans**

Regulated-party impact	Korea MFDS published change control plan guideline for digital medical devices.
SB impact	Korea digital device (SaMD) variation/change notification wizard should incorporate change control plan requirements.
Impact category	Conditional logic or pathway update
Affected pathway	Variation
Affected elements	Change control plan fields, SaMD variation wizard, digital device change categories
Required action	Compare
Enforcement date	6/26/2026
Confidence · Validation	High · Pending human validation
Official source	https://www.mfds.go.kr/brd/m_1060/view.do?seq=15874&srchFr=&...

SB-2026-162 P1 Kyrgyzstan · 6/18/2026 · Resolution of the Cabinet of Ministers of Kyrgyzstan **On Amendments to the Resolution of the Government of the Kyrgyz Republic "On the Procedure**

Regulated-party impact	Kyrgyzstan amended government resolution on device registration (EAEU alignment).
SB impact	Kyrgyzstan wizard should reflect amended resolution requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Registration pathway, EAEU alignment, Kyrgyzstan wizard
Required action	Compare
Enforcement date	6/28/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://cbd.minjust.gov.kg/7-56066/edition/54901/ru

SB-2026-163 P1 Oman · 6/28/2026 · Circular **Extension of Registration Period for High-Risk Medical Devices and Supplies Manufacturers**

Regulated-party impact	Oman extended registration period for high-risk devices.
SB impact	Oman renewal wizard timeline references should reflect extended registration period.
Impact category	Instructions/reference update
Affected pathway	Renewal
Affected elements	Renewal wizard, registration period, Oman
Required action	Compare
Enforcement date	6/28/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.moh.gov.om/media/zisn2dzq/cirno64-of-2026-regard...

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SB-2026-164

P1

Malaysia · 6/1/2026 · Notification

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

Regulated-party impact

SB impact

Impact category

Affected pathway

Affected elements

Required action

Enforcement date

Confidence · Validation

Official source

Manufacturers must submit Product Classification applications fully online from Aug 1, 2026.

Malaysia Product Classification wizard must be updated for fully online submission channel, new/renewal pathway logic, repeatable product fields, attachments, fees, and output instructions.

Conditional logic or pathway update

Classification

Submission channel, new/renewal pathway, repeatable products, attachment fields, fee references, output instructions, Malaysia classification wizard

Implement

8/1/2026

High · Pending human validation

<https://www.mda.gov.my>

SB-2026-003

P2

Mexico · 5/4/2026 · Agreement

Cofepris has published the “Agreement establishing measures to streamline procedures filed

Regulated-party impact

SB impact

Impact category

Affected pathway

Affected elements

Required action

Enforcement date

Confidence · Validation

Official source

Regulatory update requiring manual review.

Manual review required to determine SB impact.

Manual technical review

New registration

To be determined

Escalate

5/15/2026

Low · Pending human validation

https://diariooficial.gob.mx/nota_detalle.php?codigo=5786603...

SB-2026-004

P2

Mexico · 5/4/2026 · Agreement

Cofepris has published the “Agreement Updating the Methods for Submitting Applications COF

Regulated-party impact

SB impact

Impact category

Affected pathway

Affected elements

Required action

Enforcement date

Confidence · Validation

Official source

Regulatory update requiring manual review.

Manual review required to determine SB impact.

Manual technical review

New registration

To be determined

Escalate

5/5/2026

Low · Pending human validation

https://diariooficial.gob.mx/nota_detalle.php?codigo=5786604...

SB-2026-005

P2

Iraq · 5/6/2026 · Circular

Circular to Scientific Offices and Companies

Regulated-party impact

SB impact

Impact category

Affected pathway

Affected elements

Required action

Enforcement date

Confidence · Validation

Official source

Iraq circular to scientific offices and medical device companies.

Review for specific MD registration requirements. Iraq wizard references may need updating.

Instructions/reference update

New registration

Iraq wizard references

Compare

5/6/2026

Low · Pending human validation

https://drive.google.com/file/d/1OWLp6Q83DnLyBrwG4mUFT_VyB-7...

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SB-2026-012 **P2** Chile · 5/7/2026 · Resolution **Exempt Resolution No. 2.050/2026 approves the “Guidelines for Clinical Trials of Medical D**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	5/7/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.ispch.cl/wp-content/uploads/2026/05/Guia-Inv.Cli...

SB-2026-013 **P2** Chile · 5/6/2026 · Announcement **ISP Announces New Certification Program for Domestic and Innovative Medical Device Manufac**

Regulated-party impact	Chile ISP launched new certification program for domestic/innovative devices.
SB impact	Assess whether Chile wizard covers new certification pathway for domestic/innovative devices.
Impact category	New wizard or coverage-gap assessment
Affected pathway	New registration
Affected elements	New certification pathway, Chile wizard coverage gap
Required action	Monitor
Enforcement date	5/6/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.ispch.cl/noticia/isp-informa-sobre-nueva-prestac...

SB-2026-015 **P2** United States · 5/6/2026 · Guidance **Patient-Matched Guides for Orthopedic Implants**

Regulated-party impact	Manufacturers of patient-matched orthopedic implants must follow FDA guidance on design controls, labeling, and 510(k)/De Novo submissions.
SB impact	Review IVD/nIVD eSTAR wizard sections for patient-matched/custom devices. Guidance may require new conditional questions about patient-matching process.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Custom device questions, design control section, labeling fields
Required action	Compare
Enforcement date	5/7/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.fda.gov/regulatory-information/search-fda-guidan...

SB-2026-018 **P2** Switzerland · 5/1/2026 · Guidance **Manufacturer Incident Report Guideline**

Regulated-party impact	Switzerland updated manufacturer incident report guideline.
SB impact	Switzerland PMS/vigilance wizard or instructions should reference updated incident report guideline.
Impact category	Existing wizard content update
Affected pathway	Post-market/vigilance
Affected elements	Incident report fields, vigilance section
Required action	Compare
Enforcement date	5/1/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

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SB-2026-019 **P2** Switzerland · 5/1/2026 · Guidance **Information Sheet Combined Studies**

Regulated-party impact	Switzerland information sheet on combined studies (device + other).
SB impact	Switzerland clinical investigation wizard may reference updated combined study requirements.
Impact category	Instructions/reference update
Affected pathway	Clinical investigation
Affected elements	Combined study wizard, clinical investigation references
Required action	Compare
Enforcement date	5/1/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

SB-2026-025 **P2** Algeria · 5/10/2026 · Notice **Note No. 41 to Pharmaceutical Establishment and Economic Operators Relating to Requests fo**

Regulated-party impact	Algeria regulatory notice to pharmaceutical establishments and economic operators.
SB impact	Review for MD-specific requirements. Algeria MD wizard may need reference update.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Algeria wizard references
Required action	Compare
Enforcement date	5/10/2026
Confidence · Validation	Low · Pending human validation
Official source	https://drive.google.com/file/d/1oqkumGkZqFPWEfUdLA8nkXH8e1a...

SB-2026-027 **P2** Hong Kong · 5/13/2026 · Guidance **GN-00: Definitions and Abbreviations for the Medical Device Administrative Control System**

Regulated-party impact	Hong Kong updated definitions and abbreviations guidance for MDACS.
SB impact	Hong Kong wizard terminology and field labels should align with GN-00.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Field labels, definitions, wizard help text
Required action	Compare
Enforcement date	5/13/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.mdd.gov.hk/filemanager/common/mdacs/GN-00-E.pdf

SB-2026-029 **P2** Turkey · 5/13/2026 · Guidance **Guidelines for Registration Processes of Medical Devices in the Product Tracking System**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	5/13/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.titck.gov.tr/duyuru/tibbi-cihazlarin-urun-takip-...

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SB-2026-031 **P2** Paraguay · 5/13/2026 · Resolution **DINAVISA has published Resolution No. 189/2026**

Regulated-party impact	Paraguay DINAVISA published Resolution 189/2026 (details to be confirmed from source).
SB impact	Review Paraguay wizard against Resolution 189/2026 requirements.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	Paraguay MD wizard sections
Required action	Compare
Enforcement date	5/13/2026
Confidence · Validation	Low · Pending human validation
Official source	https://dinavisa.gov.py/wp-content/uploads/2026/05/RESOLUCIO...

SB-2026-032 **P2** United Kingdom · 5/11/2026 · Notification **MHRA invites Views on Proposed Changes to Medical Device Regulation**

Regulated-party impact	MHRA consultation on proposed changes to UK MD regulation.
SB impact	Monitor consultation outcome. No wizard change until final regulation published.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	All UK MD wizard sections potentially affected
Required action	Monitor
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://www.gov.uk/government/news/mhra-invites-views-on-pro...

SB-2026-034 **P2** Finland · 5/11/2026 · Notification **Medical Device Manufacturers must report Serious Incidents using a New Form**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	—
Confidence · Validation	Low · Pending human validation
Official source	https://fimea.fi/-/laakinnallisten-laitteiden-valmistajien-o...

SB-2026-036 **P2** Australia · 5/12/2026 · Guidance **Preparing for an application audit for in-vitro diagnostic medical devices**

Regulated-party impact	TGA guidance on preparing for IVD application audits.
SB impact	Australia IVD wizard audit preparation references may need updating.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	IVD wizard, audit preparation section, supporting documents
Required action	Compare
Enforcement date	N/A
Confidence · Validation	Medium · Pending human validation
Official source	https://www.tga.gov.au/resources/guidance/preparing-applicat...

SB-2026-040 P2 Peru · 5/15/2026 · Announcement **DIGEMID - Announcement No. 006/2026**

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

Peru DIGEMID announcement (details to be confirmed).
Review Peru wizard against DIGEMID Announcement 006/2026.
Instructions/reference update
New registration
Peru wizard references
Compare
5/26/2026
Low · Pending human validation
<https://www.digemid.minsa.gob.pe/webDigemid/comunicados/2026...>

SB-2026-044 P2 China · 5/8/2026 · Guidance **China NMPA Issues Guidance on Registration Review for Percutaneous Coronary Intervention P**

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

China NMPA issued final guidance for percutaneous coronary intervention devices.
China wizard product-specific technical review section for PCI devices should reference new guidance.
Existing wizard content update
New registration
PCI device technical requirements, China wizard
Compare
5/8/2026
Medium · Pending human validation
<https://www.cmde.org.cn/xwdt/shpgzgg/gztg/20260508154726128....>

SB-2026-045 P2 Ireland · 5/13/2026 · Guidance **Guide to Pre-submission Scientific and Regulatory Advice for GXP Activities**

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

Ireland HPRA guide on pre-submission advice for GXP activities.
Ireland wizard pre-submission/scientific advice references may need updating.
Instructions/reference update
New registration
Pre-submission advice references, Ireland wizard
Compare
5/13/2026
Low · Pending human validation
<https://assets.hpra.ie/data/docs/default-source/external-gui...>

SB-2026-059 P2 Mexico · 5/21/2026 · Guidelines **Guidelines for promoting National Investment in the production of Medicines, Health Produc**

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

Regulatory update requiring manual review.
Manual review required to determine SB impact.
Manual technical review
New registration
To be determined
Escalate
5/22/2026
Low · Pending human validation
https://diariooficial.gob.mx/nota_detalle.php?codigo=5788117...

SB-2026-061 **P2** Kazakhstan · 5/19/2026 · MOH Order **Order of the Minister of Health of the Republic of Kazakhstan from May 13, 2026 No. 50**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	5/29/2026
Confidence · Validation	Low · Pending human validation
Official source	https://api.gos24.kz/news/8581?title=%D0%A1+29+%D0%BC%D0%B0%...

SB-2026-063 **P2** Australia · 5/12/2026 · Notification **Preparing for an application audit for in-vitro diagnostic medical devices**

Regulated-party impact	TGA guidance on preparing for IVD application audits.
SB impact	Australia IVD wizard audit preparation references may need updating.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	IVD wizard, audit preparation section, supporting documents
Required action	Compare
Enforcement date	N/A
Confidence · Validation	Medium · Pending human validation
Official source	https://www.tga.gov.au/resources/guidance/preparing-applicat...

SB-2026-068 **P2** Korea · 5/26/2026 · Guidance for officials **Approval and Review Procedures for New Technology Medical Devices**

Regulated-party impact	Korea MFDS updated approval and review procedures for new technology medical devices.
SB impact	Korea new technology MD registration wizard should reflect updated review procedures.
Impact category	Existing wizard content update
Affected pathway	New registration
Affected elements	New technology device pathway, review procedure fields
Required action	Compare
Enforcement date	5/26/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.mfds.go.kr/brd/m_1059/view.do?seq=15241&srchFr=&...

SB-2026-069 **P2** Switzerland · 5/26/2026 · Notification **Template Trend Report**

Regulated-party impact	Switzerland updated trend report template.
SB impact	If SB includes Swiss PMS reporting, update trend report template reference.
Impact category	Official form/source-template update
Affected pathway	Post-market/vigilance
Affected elements	Trend report template, PMS wizard
Required action	Compare
Enforcement date	5/26/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

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SB-2026-070 P2 Switzerland · 5/26/2026 · Notification **Template PSR Report**

Regulated-party impact	Switzerland updated PSR (Periodic Safety Report) template.
SB impact	If SB includes Swiss PSR reporting, update PSR template reference.
Impact category	Official form/source-template update
Affected pathway	Post-market/vigilance
Affected elements	PSR template, PMS wizard
Required action	Compare
Enforcement date	5/26/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...

SB-2026-071 P2 South Africa · 5/26/2026 · Guidance **Guideline on How to Respond to a GMP, GWP, GCP or GVP Inspection Report**

Regulated-party impact	SAHPRA guideline on responding to GMP/GWP/GCP/GVP inspection reports.
SB impact	South Africa QMS/GMP evidence wizard references may need updating. GCP/GVP aspects are pharma-focused; GMP/GWP are MD-relevant.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	GMP evidence section, inspection response references
Required action	Compare
Enforcement date	5/26/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://sahpraza.sharepoint.com/:b/s/SAHPRAwebsitePublicDoc...

SB-2026-072 P2 Korea · 5/28/2026 · Guidance **FAQs for Medical Device Non-clinical Trials Guidance**

Regulated-party impact	Korea MFDS FAQ on non-clinical trial guidance for devices.
SB impact	Korea wizard technical evidence section may reference updated non-clinical testing guidance.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Non-clinical test evidence section, technical file
Required action	Compare
Enforcement date	5/28/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.mfds.go.kr/brd/m_1060/view.do?seq=15861&srchFr=&...

SB-2026-075 P2 Denmark · 5/28/2026 · Notification **Registration**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	5/28/2026
Confidence · Validation	Low · Pending human validation
Official source	https://laegemiddelstyrelsen.dk/da/udstyr/registrering/

SB-2026-078 P2 Cameroon · 5/29/2026 · Circular **Implementation of a combined Individual Case Safety Report (ICSR)/line listing system for**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	5/29/2026
Confidence · Validation	Low · Pending human validation
Official source	https://dpml.cm/index.php/fr/sinformer/actualite/annee-2026/...

SB-2026-079 P2 Iraq · 5/31/2026 · Circular **Announcement from the Pharmacy Department, Private Sector Division, to All Scientific Offi**

Regulated-party impact	Iraq pharmacy department announcement to scientific offices.
SB impact	Review Iraq wizard for relevant updates.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Iraq wizard
Required action	Monitor
Enforcement date	6/1/2026
Confidence · Validation	Low · Pending human validation
Official source	https://drive.google.com/file/d/1GNEBUgmEXgwg7N-tVOuITp7ckEh...

SB-2026-080 P2 Singapore · 5/28/2026 · Announcement **How Medical Devices are Regulated by HSA and their Safe Use**

Regulated-party impact	Singapore HSA informational publication on device regulation.
SB impact	No immediate SB action — informational only.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Wizard references
Required action	Monitor
Enforcement date	5/28/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.hsa.gov.sg/announcements/how-medical-devices-are...

SB-2026-085 P2 Argentina · 6/1/2026 · Announcement **Update on fees for ANMAT procedures**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	6/1/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.argentina.gob.ar/noticias/actualizacion-de-aranc...

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SB-2026-088 **P2** Syria · 6/3/2026 · Regulation **Regulatory Decision 8/T**

Regulated-party impact	Syria regulatory decision 8/T (details limited).
SB impact	Insufficient data to confirm SB impact. Requires manual review.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Syria wizard
Required action	Escalate
Enforcement date	6/3/2026
Confidence · Validation	Low · Pending human validation
Official source	https://drive.google.com/file/d/1ddRBamOZbzRoilCES_skJN3jq3N...

SB-2026-090 **P2** Iraq · 6/3/2026 · Circular **Circular No. 9/2/1163 To All Scientific Offices and National Factories**

Regulated-party impact	Iraq circular to scientific offices and national manufacturers.
SB impact	Review for specific requirements affecting Iraq wizard.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Iraq wizard
Required action	Monitor
Enforcement date	6/7/2026
Confidence · Validation	Low · Pending human validation
Official source	https://drive.google.com/file/d/1hGYn_qkKNyiXhTBRPQWnMKq1REx...

SB-2026-093 **P2** Uzbekistan · 5/5/2026 · President's Decree **On measures to provide additional support to the private sector in the medical field**

Regulated-party impact	Uzbekistan presidential decree on private sector support in medical field.
SB impact	Monitor for any device-specific regulatory changes resulting from this decree.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Uzbekistan wizard
Required action	Monitor
Enforcement date	5/7/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.norma.uz/novoe_v_zakonodatelstve/novye_vozmojnos...

SB-2026-096 **P2** Uzbekistan · 5/25/2026 · Legal act **Departmental regulatory legal act on the procedure for conducting inspection control of pr**

Regulated-party impact	Uzbekistan inspection control procedure regulation.
SB impact	Uzbekistan wizard GMP/inspection evidence section may need updating.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Inspection evidence, Uzbekistan wizard
Required action	Compare
Enforcement date	6/3/2026
Confidence · Validation	Low · Pending human validation
Official source	https://yuz.uz/ru/news/v-uzbekistane-ustanovlen-poryadok-ins...

SB-2026-099		P2	United States · 6/5/2026 · Guidance	Intent to Exempt Certain Unclassified Medical Devices from Premarket Notification Requirem
Regulated-party impact	FDA signals intent to exempt certain unclassified devices from 510(k). Manufacturers of affected devices may be reclassified.			
SB impact	Monitor for final rule. If exemptions finalized, classification pathway logic for affected device types may need updating.			
Impact category	Conditional logic or pathway update			
Affected pathway	Classification			
Affected elements	Device classification wizard, 510(k) pathway eligibility logic			
Required action	Monitor			
Enforcement date	—			
Confidence · Validation	Medium · Pending human validation			
Official source	https://www.fda.gov/media/89238/download			
SB-2026-106		P2	Switzerland · 6/8/2026 · Guidance	Swissdamed Machine-to-Machine REST API Technical Documentation
Regulated-party impact	Swissdamed M2M REST API documented for automated submissions.			
SB impact	If SB supports M2M submission to Swissdamed, API integration must follow published technical documentation.			
Impact category	Export/XML/data-mapping update			
Affected pathway	New registration			
Affected elements	API integration, M2M export format, authentication			
Required action	Monitor			
Enforcement date	6/5/2026			
Confidence · Validation	Medium · Pending human validation			
Official source	https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...			
SB-2026-124		P2	China · 6/5/2026 · Notification	China's NMPA Announces Removal of 10 Medical Device Industry Standards, Including Transcat
Regulated-party impact	Regulatory update requiring manual review.			
SB impact	Manual review required to determine SB impact.			
Impact category	Manual technical review			
Affected pathway	New registration			
Affected elements	To be determined			
Required action	Escalate			
Enforcement date	6/5/2026			
Confidence · Validation	Low · Pending human validation			
Official source	https://www.nmpa.gov.cn/xxgk/ggtg/ylqxgggtg/ylqxhybzhgg/20260...			
SB-2026-126		P2	Peru · 6/17/2026 · Announcement	Announcement No. 008/2026 - Webinar on the Medical Device Risk Management Report
Regulated-party impact	Peru DIGEMID webinar on MD risk management (ISO 14971).			
SB impact	Review Peru wizard risk management evidence section against DIGEMID expectations.			
Impact category	Instructions/reference update			
Affected pathway	New registration			
Affected elements	Risk management section, ISO 14971 references, Peru wizard			
Required action	Monitor			
Enforcement date	6/25/2026			
Confidence · Validation	Low · Pending human validation			
Official source	https://www.digemid.minsa.gob.pe/webDigemid/comunicados/2026...			

SB-2026-128	P2	Saudi Arabia · 6/18/2026 · Announcement	Standard Specification Annex No. (1) of the Technical Regulation for Communications and In
Regulated-party impact		Saudi Arabia standard specification annex for communication technologies in medical devices.	
SB impact		Monitor — may affect technical specifications section for connected/communication-enabled devices.	
Impact category		Watchlist—draft or unverified	
Affected pathway		New registration	
Affected elements		Technical specifications, connected device fields	
Required action		Monitor	
Enforcement date		11/1/2026	
Confidence · Validation		Medium · Pending human validation	
Official source		https://drive.google.com/file/d/10dstW9MxHscAWGiYnmxCNleQ4oz...	

SB-2026-134	P2	Switzerland · 6/19/2026 · Notification	Amendment to the Swissmedic Fee Ordinance as of July 1, 2026
Regulated-party impact		Swissmedic fee ordinance amended as of July 1, 2026. Per-UDI-DI fees apply.	
SB impact		Switzerland wizard should reflect updated fee schedule and per-UDI-DI fee logic.	
Impact category		Instructions/reference update	
Affected pathway		New registration	
Affected elements		Fee fields, fee schedule references	
Required action		Compare	
Enforcement date		7/1/2026	
Confidence · Validation		Medium · Pending human validation	
Official source		https://www.swissmedic.ch/swissmedic/de/home/news/mitteilung...	

SB-2026-135	P2	Switzerland · 6/19/2026 · Guidance	Procurement of Medical Devices in Healthcare Facilities
Regulated-party impact		Regulatory update requiring manual review.	
SB impact		Manual review required to determine SB impact.	
Impact category		Manual technical review	
Affected pathway		New registration	
Affected elements		To be determined	
Required action		Escalate	
Enforcement date		5/19/2026	
Confidence · Validation		Low · Pending human validation	
Official source		https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...	

SB-2026-136	P2	Switzerland · 6/19/2026 · Guidance	Swissdamed User Guide - Playground
Regulated-party impact		Swissdamed playground environment available for testing.	
SB impact		Operational note for SB implementation/testing team — playground can be used to validate Swissdamed submissions.	
Impact category		Instructions/reference update	
Affected pathway		New registration	
Affected elements		Testing instructions	
Required action		Monitor	
Enforcement date		6/19/2026	
Confidence · Validation		Low · Pending human validation	
Official source		https://www.swissmedic.ch/dam/swissmedic/de/dokumente/medizi...	

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In-Scope MD/IVD/Combination Device Alerts

Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-138 **P2** Sweden · 6/17/2026 · News **The Swedish Medicines Agency will be responsible for AI systems in medical devices.**

Regulated-party impact	Sweden MPA to take responsibility for AI systems in medical devices.
SB impact	Monitor — may affect SaMD/AI-MD wizard classification and regulatory pathway in Sweden.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	AI/SaMD pathway, Sweden wizard
Required action	Monitor
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://www.lakemedelsverket.se/sv/nyheter/lakemedelsverket-...

SB-2026-139 **P2** European Union · 6/17/2026 · Guidance **Guidance on standardisation for medical devices**

Regulated-party impact	EU guidance on use of harmonized standards for conformity assessment.
SB impact	May affect standards references in EU MDR/IVDR technical file wizard sections.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Standards references, essential requirements section, harmonized standards list
Required action	Monitor
Enforcement date	—
Confidence · Validation	Medium · Pending human validation
Official source	https://health.ec.europa.eu/document/download/59ac4cb0-f187-...

SB-2026-141 **P2** Bahrain · 6/9/2026 · Circular **Updated Fee Schedules of Services and Requests for Medical Devices and Products in the Nat**

Regulated-party impact	Bahrain NHRA updated fee schedule for MD services.
SB impact	Update Bahrain wizard fee references if fee information is included in wizard.
Impact category	Instructions/reference update
Affected pathway	New registration
Affected elements	Fee fields, fee schedule references
Required action	Compare
Enforcement date	6/9/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.nhra.bh/Departments/MDR/MediaHandler/GenericHand...

SB-2026-144 **P2** Australia · 6/22/2026 · Notification **New UDI Newsletter**

Regulated-party impact	TGA UDI newsletter published.
SB impact	Review for any actionable UDI updates. Update wizard references if needed.
Impact category	Instructions/reference update
Affected pathway	UDI
Affected elements	UDI wizard references
Required action	Monitor
Enforcement date	N/A
Confidence · Validation	Low · Pending human validation
Official source	https://www.tga.gov.au/products/medical-devices/labelling-an...

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In-Scope MD/IVD/Combination Device Alerts

Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-145 P2 Australia · 6/22/2026 · Notification **Getting started with UDI**

Regulated-party impact	TGA getting started with UDI guidance.
SB impact	Update Australia UDI onboarding instructions.
Impact category	Instructions/reference update
Affected pathway	UDI
Affected elements	UDI wizard onboarding/help text
Required action	Compare
Enforcement date	N/A
Confidence · Validation	Low · Pending human validation
Official source	https://www.tga.gov.au/products/medical-devices/labelling-an...

SB-2026-159 P2 Bolivia · 6/25/2026 · Circular **CIRCULAR-22-2026**

Regulated-party impact	Regulatory update requiring manual review.
SB impact	Manual review required to determine SB impact.
Impact category	Manual technical review
Affected pathway	New registration
Affected elements	To be determined
Required action	Escalate
Enforcement date	6/25/2026
Confidence · Validation	Low · Pending human validation
Official source	https://www.agemed.gob.bo/img/matinf/CIRCULAR-22-2026_1.jpg

SB-2026-006 Watchlist China · 5/6/2026 · Draft for Comment **NMPA Seeks Public Comments on Three Medical Device Registration Review Guidelines**

Regulated-party impact	China NMPA draft registration review guidelines for public comment.
SB impact	Monitor — no wizard change until final publication.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	China wizard, product-specific technical review sections
Required action	Monitor
Enforcement date	5/6/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/xwdt/zxyw/20260506085647159.html

SB-2026-054 Watchlist Kazakhstan · 5/19/2026 · Draft **Resolution of the Government of the Republic of Kazakhstan "On the draft Law of the Republ**

Regulated-party impact	Kazakhstan draft law amendment.
SB impact	Monitor — no wizard change until final.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Kazakhstan wizard
Required action	Monitor
Enforcement date	6/4/2026
Confidence · Validation	Low · Pending human validation
Official source	https://legalacts.egov.kz/npa/view?id=15829836

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In-Scope MD/IVD/Combination Device Alerts

Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-055

Watchlist

Kazakhstan · 5/19/2026 · Draft

On Amendments to the Order of the Minister of Health of the Republic of Kazakhstan dated S

Regulated-party impact	Kazakhstan draft amendment to Ministry of Health order on medical devices.
SB impact	Monitor — no wizard change until final.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Kazakhstan wizard
Required action	Monitor
Enforcement date	6/4/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://legalacts.egov.kz/npa/view?id=15829812

SB-2026-056

Watchlist

China · 5/12/2026 · Draft for Comment

China Seeks Public Comment on Draft Registration Review Guidance for Anastomosis Reinforce

Regulated-party impact	China NMPA draft guidance for anastomosis devices.
SB impact	Monitor — no wizard change until final.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Product-specific technical sections
Required action	Monitor
Enforcement date	5/12/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/flfg/zdyz/zqyjg/20260512172630174.ht...

SB-2026-057

Watchlist

China · 5/11/2026 · Draft for Comment

China Seeks Public Comment on Draft Registration Review Guidance for Four Medical Device C

Regulated-party impact	China NMPA draft guidance for four device categories.
SB impact	Monitor — no wizard change until final.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Product-specific sections
Required action	Monitor
Enforcement date	5/11/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/flfg/zdyz/zqyjg/20260511173904118.ht...

SB-2026-058

Watchlist

China · 5/6/2026 · Draft for Comment

China Releases Draft Guidance for Public Comment on Three Medical Device Registration Revi

Regulated-party impact	China NMPA draft guidance for three device categories.
SB impact	Monitor — no wizard change until final.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Product-specific sections
Required action	Monitor
Enforcement date	5/6/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/flfg/zdyz/zqyjg/20260506085647159.ht...

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In-Scope MD/IVD/Combination Device Alerts
Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-064 Watchlist Kazakhstan · 5/22/2026 · Draft **On amendments and additions to the joint order of the Minister of Artificial Intelligence**

Regulated-party impact	Draft regulation or guidance open for consultation.
SB impact	No wizard change until final publication.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	N/A
Required action	Monitor
Enforcement date	5/27/2026
Confidence · Validation	Low · Pending human validation
Official source	https://legalacts.egov.kz/npa/view?id=15833365

SB-2026-103 Watchlist Nicaragua · 6/8/2026 · Regulation **Public Consultation 175 - (NTON) 24001**

Regulated-party impact	Nicaragua draft technical standard for public consultation.
SB impact	Monitor — no wizard change until final publication.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Technical standard references
Required action	Monitor
Enforcement date	6/8/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.minsa.gob.ni/sites/default/files/publicaciones/C...

SB-2026-110 Watchlist China · 6/3/2026 · Draft for Comment **China NMPA Seeks Public Input on Four Draft Medical Device Registration Review Guidelines**

Regulated-party impact	China NMPA draft for four device categories.
SB impact	Monitor — no wizard change until final.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Product-specific sections
Required action	Monitor
Enforcement date	6/3/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/flfg/zdyz/zqyjg/20260603133519169.ht...

SB-2026-111 Watchlist China · 6/10/2026 · Draft for Comment **China NMPA Opens Public Consultation on Draft Registration Review Guidelines for Infant Ra**

Regulated-party impact	China NMPA draft review guidelines.
SB impact	Monitor — no wizard change until final.
Impact category	Watchlist—draft or unverified
Affected pathway	New registration
Affected elements	Product-specific sections
Required action	Monitor
Enforcement date	6/10/2026
Confidence · Validation	Medium · Pending human validation
Official source	https://www.cmde.org.cn/flfg/zdyz/zqyjg/20260610090641163.ht...

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In-Scope MD/IVD/Combination Device Alerts

Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-114

Watchlist

Kazakhstan · 6/10/2026 · Draft Order

On amendments to the order of the Minister of Health of the Republic of Kazakhstan dated F

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

Kazakhstan draft amendment to Ministry of Health order on medical devices.
Monitor — no wizard change until final.
Watchlist—draft or unverified
New registration
Kazakhstan wizard
Monitor
6/25/2026
Medium · Pending human validation
<https://legalacts.egov.kz/npa/view?id=15846787>

SB-2026-119

Watchlist

Korea · 6/12/2026 · Draft

Medical Device Manufacturing and Quality Control Standards

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

Korea MFDS draft QMS standards for device manufacturing.
Monitor — no wizard change until final publication.
Watchlist—draft or unverified
New registration
QMS evidence section
Monitor
TBD
Medium · Pending human validation
https://www.mfds.go.kr/brd/m_209/view.do?seq=44254&srchFr=&s...

SB-2026-148

Watchlist

Brazil · 6/23/2026 · Circular

ANVISA Opens Public Call for Proposals to Improve Technovigilance Rules in Brazil.

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

ANVISA consultation on improving technovigilance rules.
Monitor — no wizard change until final.
Watchlist—draft or unverified
Post-market/vigilance
PMS/vigilance wizard references
Monitor
6/23/2026
Low · Pending human validation
<https://www.gov.br/anvisa/pt-br/assuntos/noticias-anvisa/202...>

SB-2026-150

Watchlist

Kyrgyzstan · 6/25/2026 · Draft

Government's Decree

Regulated-party impact
SB impact
Impact category
Affected pathway
Affected elements
Required action
Enforcement date
Confidence · Validation
Official source

Kyrgyzstan draft government decree.
Monitor — no wizard change until final.
Watchlist—draft or unverified
New registration
Kyrgyzstan wizard
Monitor
7/17/2026
Low · Pending human validation
<https://koomtalkuu.gov.kg/ru/view-mpa/6316>

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In-Scope MD/IVD/Combination Device Alerts
Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

SB-2026-153	Watchlist	China · 6/17/2026 · Draft for Comment	China's NMPA Invites Industry Participation in Drafting Registration Review Guidelines for
Regulated-party impact	China NMPA invitation to participate in drafting guidance.		
SB impact	Monitor — no wizard change until final.		
Impact category	Watchlist—draft or unverified		
Affected pathway	New registration		
Affected elements	Product-specific sections		
Required action	Monitor		
Enforcement date	6/17/2026		
Confidence · Validation	Low · Pending human validation		
Official source	https://www.cmde.org.cn/xwdt/zxyw/20260617133619179.html		

SB-2026-104	No SB action	Lebanon · 6/9/2026 · Circular	Circular No. 22 Regarding the Entry of Import Invoices for Non-Implanted Medical Devices o
Regulated-party impact	Lebanon import invoice entry requirement for non-implanted devices — administrative logistics.		
SB impact	No SB action — administrative import invoice requirement, not a registration dossier change.		
Impact category	No SB impact		
Affected pathway	N/A		
Affected elements	N/A		
Required action	Close		
Enforcement date	8/9/2026		
Confidence · Validation	High · Pending human validation		
Official source	https://www.moph.gov.lb/files/laws/files/Tamim_22_2026.pdf		

SB-2026-113	No SB action	Singapore · 6/11/2026 · Notification	Mean Applicant Screening Response Time Audiences
Regulated-party impact	Singapore HSA performance metrics publication.		
SB impact	No SB action — administrative performance data, no regulatory delta.		
Impact category	No SB impact		
Affected pathway	N/A		
Affected elements	N/A		
Required action	Close		
Enforcement date	6/11/2026		
Confidence · Validation	High · Pending human validation		
Official source	https://www.hsa.gov.sg/announcements/mean-applicant-screenin...		

SB-2026-149	No SB action	Denmark · 6/18/2026 · Notification	Fees for Clinical Trials of Medical Devices
Regulated-party impact	Denmark fee schedule for clinical trials.		
SB impact	No SB action — administrative fee schedule.		
Impact category	No SB impact		
Affected pathway	N/A		
Affected elements	N/A		
Required action	Close		
Enforcement date	—		
Confidence · Validation	High · Pending human validation		
Official source	https://laegemiddelstyrelsen.dk/da/udstyr/klinisk-afproevnin...		

Annex — Excluded Alerts

44 Alerts Excluded (Pharma-only or Out of Scope)

Medical Devices · IVDs · Combination Devices | May–July 2026 | Pharma excluded

These alerts were reviewed and excluded because they relate to pharmaceutical-only regulations, administrative/fee matters, cybersecurity incidents, or other topics outside the MD/IVD Submission Builder scope.

Alert ID	Market	Published	Alert Title	Reason for Exclusion
SB-EX-001	Chile	5/7/2026	Exempt Resolution No. E1.199/2026 approves the services and fees of th	Fee schedule — administrative only
SB-EX-002	Pakistan	5/10/2026	Implementation of Online System for Submission and Processing of Appel	Pharma-only or out-of-scope: drug
SB-EX-003	Guyana	5/11/2026	The Guyana Electronic Single Window (GESW) for permits, licenses, and	Pharma-only or out-of-scope: single window
SB-EX-004	Argentina	5/13/2026	ANMAT promotes Regional Regulatory Cooperation and Regulatory updates	Pharma-only or out-of-scope: anmat promotes regional
SB-EX-005	Finland	5/18/2026	The NIS2 Operator Notification is made in Fimea's Electronic Services.	Pharma-only or out-of-scope: nis2 operator
SB-EX-006	Algeria	5/19/2026	Note No. 44 to Pharmaceutical Establishment Requirement for Tax Cleara	Pharma-only or out-of-scope: pharmaceutical
SB-EX-007	Argentina	5/19/2026	ANMAT updates fees and reduces costs for 75% of importers of medicines	Pharma-only or out-of-scope: medicine
SB-EX-008	Turkey	5/20/2026	Attention of Clinical Trial Parties	Clinical trial administrative notice — pharma focus, no SB registration impact
SB-EX-009	Brazil	5/19/2026	ANVISA Launches DUIMP Queue Dashboard and Issues Guidance on Filing Co	Pharma-only or out-of-scope: duimp queue
SB-EX-010	Turkey	5/20/2026	Attention of Clinical Trial Parties	Clinical trial administrative notice — pharma focus, no SB registration impact
SB-EX-011	Italy	5/20/2026	Injectable Fillers: Clarifications on Distribution and Sales Methods	Pharma/cosmetic distribution clarification — out of scope
SB-EX-012	Brazil	5/21/2026	Importation No. 048/2026	Import circular — administrative logistics, no dossier impact
SB-EX-013	Egypt	5/24/2026	Progress Follow-Up Report Template Clinical Trial of an Investigationa	Pharma-only or out-of-scope: progress follow-up report template clinical trial of an investigational
SB-EX-014	Algeria	5/24/2026	Note No. 45 to Pharmaceutical Establishments on Submission of Tax Clea	Tax clearance administrative requirement — no dossier impact
SB-EX-015	Ecuador	5/22/2026	Organic Law for Strengthening Cibersecurity	Pharma-only or out-of-scope: cibersecurity
SB-EX-016	Chile	5/25/2026	ISP and CORFO Launch Strategic Project to Strengthen Medical Device Re	Strategic investment announcement — no regulatory delta
SB-EX-017	Sweden	5/26/2026	The Swedish Medicines Agency Strengthens Preparedness – Surveys the Me	General preparedness survey — no immediate regulatory delta
SB-EX-018	Sweden	5/26/2026	Registration of Invoicing Details for Economic Operators Registered in	Administrative invoicing — no registration dossier impact
SB-EX-019	India	5/26/2026	Regulatory Guidelines for Sampling of Drugs, Cosmetics & Medical Devic	Sampling guidance for drugs/cosmetics — pharma-focused
SB-EX-020	Denmark	5/28/2026	Registration Fee	Pharma-only or out-of-scope: medicine
SB-EX-021	Colombia	5/28/2026	Invima Hosts a Conference on Healthcare Technologies from a Regulatory	General conference announcement — no regulatory delta
SB-EX-022	Tanzania	5/31/2026	Explanation of the Challenges of the New Joint Load Relief System (TAN	Customs logistics system — not MD registration scope
SB-EX-023	Denmark	5/28/2026	Annual Fee	Pharma-only or out-of-scope: medicine
SB-EX-024	United States	6/2/2026	Drug and Device Manufacturer Communications With Payors, Formulary Com	Drug-device communication guidance (mainly pharma payors) — out of scope
SB-EX-025	Germany	5/28/2026	Instructions for those Required to Report Address Ads	Pharma-only or out-of-scope: address ads
SB-EX-026	Australia	6/3/2026	Annual charge waiver guidelines - How to apply for an annual charge wa	Pharma-only or out-of-scope: annual charge waiver
SB-EX-027	Algeria	5/31/2026	Regulatory Inspections Guideline	Pharma-only or out-of-scope: pharmaceutical

SB-EX-028	Bolivia	6/8/2026	Cyber Attack at AGEMED Systems	Cybersecurity incident — no registration impact
SB-EX-029	Qatar	6/9/2026	Customs Union Authority Launches "Taysir" System to Address Trade Obst	Pharma-only or out-of-scope: customs union
SB-EX-030	Botswana	6/10/2026	Notice of Implementation of a Combined Screening and Evaluation Proces	Pharma-only or out-of-scope: medicine
SB-EX-031	Latvia	6/9/2026	The Government Supports the Consolidation of Supervision of the Pharma	Pharma-only or out-of-scope: pharmaceutical
SB-EX-032	South Africa	6/10/2026	Guideline on Minimum Requirements for Inspecting Group III and Group I	Hazardous substances inspection — not MD registration scope
SB-EX-033	South Africa	6/11/2026	Application for Authority for the Temporary Use, Possession and Transp	Pharma-only or out-of-scope: temporary use, possession and transport of equ
SB-EX-034	Algeria	6/11/2026	Note to Pharmaceutical Institutions	Pharma-only or out-of-scope: pharmaceutical
SB-EX-035	Lithuania	6/10/2026	Information Regarding a Cyber Incident	Pharma-only or out-of-scope: cyber incident
SB-EX-036	Lithuania	6/10/2026	VASPTV Informs About the Controlled Cyber Incident in the Information	Pharma-only or out-of-scope: cyber incident
SB-EX-037	Norway	6/12/2026	Medical Device Supervision Shows Challenges with Cosmetic Clinics and	Market surveillance report — no dossier change required
SB-EX-038	United States	6/16/2026	TESTING ISSUES	Test/sandbox entry — not a real alert
SB-EX-039	Australia	6/18/2026	TGA Releases New Guidance on Advertising Restrictions for Prescription	Pharma advertising — out of scope
SB-EX-040	South Africa	6/15/2026	Guideline on Minimum Requirements for Inspecting Group III and Group I	Hazardous substances inspection — not MD registration scope
SB-EX-041	Costa Rica	6/18/2026	Digital systems will be temporarily out of service	Pharma-only or out-of-scope: digital systems
SB-EX-042	Bolivia	6/22/2026	AGEMED/CE/021/2026	General administrative circular — insufficient data
SB-EX-043	Bolivia	6/22/2026	MSyD/AGEMED/CR/19/2026	General administrative circular — insufficient data
SB-EX-044	Kuwait	6/13/2026	Electronic Invoice Release Platform Companies` User Manual	Pharma-only or out-of-scope: pharmaceutical