

REGDESK REGULATORY INTELLIGENCE

Regulatory Alerts Dossier Impact Assessment

May – July 2026

123

Total
Alerts

45+

Markets

54

P0
Immediate

30

P1 Urgent

23

P2
Planning

16

P3 Watch

Generated: July 2026 | Confidential — RegDesk Internal Use

54

P0 — Immediate
Already in force

30

P1 — Urgent
<3 months to enforce

23

P2 — Planning
3–6 months

16

P3 — Watch
Drafts / No deadline Top Headline Events (P0)

- **EUDAMED mandatory from May 28** — all EU markets, Turkey, Switzerland affected; DMIDS replaced
- **Switzerland Swissdamed mandatory July 1** — registration fees introduced; new UDI tools available
- **Bahrain MADAR 2.0 (May 1) + TATABU traceability** — unregistered device catalogue due July 31
- **USA FDA eSTAR Human Factors update** — enforcement August 1, 2026; nIVD and IVD affected
- **Korea Medical Device Act Enforcement Decree** — effective July 1; Regional FDAs can revoke conformity assessments
- **EU Implementing Regulation 2026/977** — new notified body QMS requirements; effective May 4
- **Belarus regulatory transfer to Gospharmnadzor** — effective July 1; redirect all submissions
- **New MIR form v7.3.1 mandatory** — all EU serious incident reports from May 2026

 Key Themes

- **EUDAMED ecosystem expansion** — EU, EEA, Turkey, and Switzerland all converging on EUDAMED/Swissdamed
- **UDI & traceability acceleration** — Bahrain TATABU, Turkey ÜTS, Australia AusUDID, Egypt EDA UDI, EU MDCG 2026-5
- **Digital health & SaMD/AI** — Kenya, India, Sweden, Ethiopia, Korea all publish new software MD guidance
- **Clinical trial modernization** — Chile, Egypt, Korea (RWE), UK (IEC 62304), Malaysia-Thailand reliance programme
- **Regulatory reliance programs** — Malaysia-Thailand pilot, TGA comparable overseas assessments, Mexico equivalence pathway
- **China mass regulatory output** — 57 registration review guidelines + 4 standard amendments + 3 UDI guidance drafts
- **Ethiopia new market entry** — 13 comprehensive guidelines cover full regulatory lifecycle
- **PMS/Vigilance tightening** — Oman, Egypt, Ethiopia, Italy, Saudi Arabia all publish new vigilance frameworks



Alert Detail — Dossier Impact Assessment (All 123 Alerts)

Country	Date	Type	Title	Pri.	Domain	Dossier Sections	Action Required
Canada	May 4	Notice	Mandatory REP for MD submissions	P0	Registration	Submission Dossier	Use REP for all new MD submissions to Health Canada
Canada	May 4	Guidance	Updated guidance for new/amended MD licence applications	P3	Registration	Submission Dossier	Review updated application requirements
Canada	May 4	Guidance	Private label MD licence application guidance updated	P3	Registration	Submission Dossier	Review private label submission requirements
Malaysia	May 1	Notification	Malaysia-Thailand Reliance Programme (3-month pilot)	P2	Registration	Submission Dossier	Assess reliance pathway eligibility for dual-market submissions
Kazakhstan	May 4	Draft	Amended rules for MD inspections — early-stage inspection, risk-based classification	P3	QMS/GMP	QMS	Monitor final publication; review QMS documentation readiness
Bahrain	May 5	Circular	NHRA Traceability Program introduced (Circular 5/2026)	P0	UDI/Traceability	UDI / Traceability	Register in TATABU by June 21; mandatory from July 1
Turkey	May 5	Announcement	EUDAMED mandatory — impacts ÜTS registration and device tracking	P0	Registration / UDI	Registration / UDI	Align ÜTS submissions with EUDAMED; update device registrations
Panama	May 5	Regulation	Resolution 0277/2026 — radiation-emitting device registration	P0	Registration	Registration / Technical File	Notify, register and license radiation-emitting devices per new procedure
Ecuador	May 5	Resolution	ARCSA 2026-003 — new MD registration regulation; enforcement Jan 28, 2027	P1	Registration	Registration / Technical File	Begin dossier alignment with new requirements; plan resubmissions
Mexico	May 5	Agreement	Cofepris streamlining — clarified requirements and timelines; effective May 15	P0	Registration	Submission Dossier	Update submission checklists per new Cofepris requirements
Mexico	May 5	Agreement	Cofepris updates research protocol submission procedures (COFEPRIS-04-010/09-012)	P0	Clinical Trials	Clinical Trials	Use updated COFEPRIS forms for research protocol submissions
Iraq	May 6	Circular	Online booking mandatory for registration dept. visits (from May 1)	P0	Registration	Import/Export	Book visits online via registration portal; no walk-ins accepted
China	May 6	Draft	NMPA consultation on 3 Class II device guidelines (meniscal suture, orthodontic screw, cervical disc)	P3	Registration	Technical File / Clinical Eval	Participate in consultation if relevant; monitor for final publication
China	May 6	Guidance	5 new Class III guidelines: cardiovascular coils, IVC filters, balloons, thrombectomy stents, hemodialyzers	P1	Registration	Technical File / Clinical Eval	Update technical dossiers for affected cardiovascular devices
China	May 6	Draft	Clinical-exemption catalogue revision — 70+ new entries across MD and IVD categories	P3	Registration	Technical File	Review updated clinical exemption eligibility for applicable products
China	May 6	Draft	Positive cutoff value guideline for tumor gene detection IVD reagents	P3	Registration	Technical File / Clinical Eval	Align IVD dossier analytical section with updated guideline when finalized
Australia	May 6	Guidance	AusUDID guidance — access, submission methods, data elements	P1	UDI/Traceability	UDI / Traceability	Set up AusUDID access; submit UDI records per updated requirements
Uzbekistan	May 6	MOH Order	Amended MD classification by type and risk level; effective May 2	P0	Registration	Technical File / Registration	Verify device classification under new nomenclature; update registration if affected
Saudi Arabia	May 7	Guidance	MDS-G028 — Bundling criteria for MD MDMA applications	P2	Registration	Submission Dossier	Apply bundling guidance for multi-device MDMA submissions
Chile	May 7	Resolution	GCP guidelines for clinical trials of medical devices (Resolution 2050/2026)	P0	Clinical Trials	Clinical Trials	Align clinical trial protocols with new Chilean GCP requirements
Chile	May 7	Resolution	ISP fees for MD sanitary control updated (Resolution E1.199/2026)	P0	Registration	Registration	Update budget for ISP submissions with revised fee schedule

Country	Date	Type	Title	Pri.	Domain	Dossier Sections	Action Required
Chile	May 6	Announcement	ISP launches certification program for domestic/innovative MD manufacturers	P3	QMS/GMP	QMS	Relevant for domestic/innovative MD manufacturers seeking ISP certification
Spain	May 7	Notification	AEMPS updates vigilance system and healthcare center surveillance responsibilities	P2	PMS/Vigilance	PMS / Vigilance	Review and update PMS/vigilance reporting responsibilities in Spain
USA (FDA)	May 7	Guidance	Patient-Matched Guides for Orthopedic Implants — premarket submission guidance	P0	Registration	Technical File / Clinical Eval	Include in premarket submissions for patient-matched orthopedic guides
EU	May 5	Guidance	Implementing Regulation 2026/977 — notified body QMS/procedural requirements (Annex VII)	P0	Registration	Technical File / QMS	Assess impact on NB timelines and certification strategy; recertification implications
Czech Republic	May 7	Guidance	MDR requirements for custom-made devices in dental labs; effective June 1	P0	Registration	Technical File	Implement MDR CMD requirements in dental lab procedures
Denmark	May 7	Notification	Drug-device combo — NB consultation application form updated	P2	Registration	Technical File / Clinical Eval	Use updated form for NB consultation on ancillary medicinal substances
Switzerland	May 7	Guidance	Swissmedic MIR guideline — specific incident report requirements; effective May 1	P0	PMS/Vigilance	PMS / Vigilance	Update incident reporting procedures to Swissmedic
Switzerland	May 7	Guidance	Combined studies information sheet for sponsors/CROs/investigators	P2	Clinical Trials	Clinical Trials	Reference for combined clinical trials in Switzerland
Korea	May 7	Regulation	MD Approval, Notification & Review — RWE expanded; no notarization for foreign translations	P0	Registration	Technical File / Clinical Eval	Leverage RWE pathway; remove notarization requirement for foreign data
Korea	May 7	Guideline	Digital MD Clinical Trial Guideline — data-based trial exemption criteria	P2	Clinical Trials	Clinical Trials	Review exemption criteria for digital MD clinical trials
Saudi Arabia	May 8	Forms	SFDA updated: CAPA form, Risk Assessment form, FSCA Closure Report form	P0	PMS/Vigilance	PMS / Vigilance	Use updated SFDA forms for all CAPA, risk assessment, and FSCA submissions
Turkey	May 8	Announcement	Turkey aligning EU Implementing Regulation 2026/977 for NB requirements	P2	Registration	Technical File / QMS	Monitor Turkey NB alignment; adjust certification timelines if needed
Pakistan	May 8	Notification	DRAP digital portal — discourage third-party consultants; all functions digitized	P0	Registration	Submission Dossier	Submit directly via DRAP CMS; no third-party consultant access
Australia	May 11	Guidance	Using overseas regulator assessments for MD applications — TGA reliance pathway	P2	Registration	Submission Dossier	Leverage TGA reliance pathway using recognized overseas assessments
Australia	May 11	Guidance	Market authorization evidence from comparable overseas regulators (incl. IVDs)	P2	Registration	Submission Dossier	Leverage IVD reliance pathway for applicable products
Switzerland	May 11	Guidance	Swissdamed User Manual updated — CH-login and AGOV-login access	P0	Registration	Registration	Update access credentials per new Swissdamed login requirements
Brazil	May 12	Circular	IMDRF public consultation — Supplier Quality Control guideline; deadline July 6	P3	QMS/GMP	QMS	Submit comments to IMDRF if applicable; monitor final guideline
Algeria	May 12	Notice	Note 41 — documentation requirements for product classification requests	P1	Registration	Technical File / Registration	Ensure classification request documentation meets updated requirements
Algeria	May 12	Notice	Note 42 — mandatory labeling and packaging information requirements	P1	Labeling	Labeling & IFU	Review and update labeling/packaging for Algeria to meet updated requirements
Pakistan	May 13	Announcement	Online Appellate Board appeals — hardcopy discontinued; effective May 15	P0	Registration	Submission Dossier	Submit all appeals electronically via DRAP online system

Country	Date	Type	Title	Pri.	Domain	Dossier Sections	Action Required
Hong Kong	May 13	Guidance	GN-00 MDACS definitions revised — new appendix added	P2	Registration	Submission Dossier	Review updated MDACS definitions for listing applications
Guyana	May 13	Announcement	Guyana Electronic Single Window (GESW) launched for import/export	P0	Import/Export	Import/Export / Distribution	Use GESW portal for import/export permits and customs declarations
Egypt	May 14	Guideline	EDA UDI requirements for medical devices and IVDs	P1	UDI/Traceability	UDI / Labeling & IFU	Align UDI implementation with EDA requirements; update device labeling
Turkey	May 14	Guidance	Updated guidelines for MD registration in ÜTS product tracking system	P0	Registration / UDI	Registration / UDI	Follow updated ÜTS registration process for all MD submissions
Nicaragua	May 14	Regulation	New Importation/Exportation form for regulated products	P0	Import/Export	Import/Export	Use new MINSa import/export form for all regulated product submissions
Paraguay	May 14	Resolution	DINAVISA Resolution 189/2026 — health risk calculation parameters for sanctions	P2	Registration	Submission Dossier	Understand risk parameters used in DINAVISA enforcement decisions
UK	May 13	Notification	MHRA consultation on proposed pre-market MD regulation changes	P2	Registration	Technical File / Submission Dossier	Participate in MHRA consultation; monitor for new pre-market requirements
UK	May 14	Guidance	MD Conformity Assessment and UKCA Mark — updated flow chart for assessment routes	P1	Registration	Technical File / Registration	Verify conformity assessment route via updated UKCA flow chart
Finland	May 12	Notification	MIR form v7.3.1 mandatory from May 2026 — new serious incident form	P0	PMS/Vigilance	PMS / Vigilance	Implement new MIR form for all serious incident reports in EU
Bahrain	May 15	Circular	TATABU Traceability System launch — registration portal open May 13	P0	UDI/Traceability	UDI / Traceability	Register in TATABU; complete onboarding per regulatory deadlines
Bahrain	May 15	Circular	Mandatory NHRA Traceability Program — deadline June 21; mandatory July 1	P0	UDI/Traceability	UDI / Traceability	Complete mandatory traceability registration by June 21, 2026
Bahrain	May 15	Circular	MADAR 2.0 replaces AHJEZA — effective May 1, 2026	P0	Registration	Registration	Transition all MD regulatory submissions to MADAR 2.0 platform
USA (FDA)	Jun 1	Guidance	eSTAR updated — Human Factors content added; PreSTAR available; enforcement Aug 1	P0	Registration	Submission Dossier / Technical File	Update eSTAR dossier with Human Factors content per new guidance; deadline Aug 1
Czech Republic	Jun 1	Guideline	MDR custom-made device guideline for dental labs effective June 1	P0	Registration	Technical File	Implement in dental laboratory CMD procedures
Syria	Jun 3	Regulation	Regulatory Decision 8/T — importation technical approval requirements	P0	Import/Export	Import/Export	Comply with technical approval requirements for importation into Syria
Oman	Jun 3	Regulation	Optical companies — Class D high-risk products must be registered; clearance linked to approval	P0	Registration	Registration	Ensure Class D ophthalmic/optical devices are registered before clearance
Iraq	Jun 3	Circular	Electronic booking for registration department (from June 7)	P0	Registration	Registration	Book all registration visits electronically via IFDA portal
Switzerland	Jun 2	Guidance	Swissdamed Business Rules — aligned with EUDAMED structure	P0	Registration	Registration / UDI	Apply Swissdamed business rules for product registration and UDI management
Uzbekistan	Jun 3	Legal act	ISO 13485 compliance required for MD production inspection during registration	P0	QMS/GMP	QMS	Ensure ISO 13485 QMS is documented and ready for Uzbekistan registration inspection
Germany	May 28	Notification	EUDAMED mandatory from May 28 — DMIDS replaced for all MD/IVD registrations	P0	Registration / UDI	Registration / UDI	All German MD/IVD registrations must now be done in EUDAMED
South Africa	Jun 4	Guidance	e-IFU requirements for MDs and IVDs — SAHPRA guidance	P1	Labeling	Labeling & IFU	Review e-IFU implementation against SAHPRA requirements; update IFU documentation

Country	Date	Type	Title	Pri.	Domain	Dossier Sections	Action Required
Singapore	Jun 2	Guidance	GN-12-1 MD Grouping — scope expanded to all MDs under Act definition	P2	Registration	Submission Dossier	Apply updated grouping criteria for Singapore product registration
Algeria	May 31	Guidance	Regulatory Inspections Guideline — GPP procedures throughout supply chain	P2	QMS/GMP	QMS / Import/Export	Review GDP/GPP compliance for Algeria supply chain activities
Algeria	May 13	Guidance	Regulatory Trust/Reliance for GMP Inspections — framework guidance	P2	QMS/GMP	QMS	Leverage reliance framework to reduce inspection burden in Algeria
Nicaragua	Jun 8	Regulation	Public Consultation on NTON 24001 — MD sanitary registration standard; closes July 1	P3	Registration	Technical File / Registration	Monitor finalization; align dossier with updated NTON requirements
Lebanon	Jun 9	Circular	Circular 22 — non-implantable MD import invoices via MEDIMPORT; enforcement Aug 9	P1	Import/Export	Import/Export / Distribution	Register and submit non-implantable MD import invoices in MEDIMPORT
Lebanon	Jun 9	Circular	Circular 23 — FDA-approved implantables: unused device removal via MEDTRACE	P1	Import/Export	Import/Export / Distribution	Submit removal requests for unused FDA-approved implantables via MEDTRACE
Kenya	Apr 16	Guidance	MDSW/SaMD/SiMD regulation guideline — PPB Kenya	P2	Software (SaMD/AI)	Technical File / Software	Classify and register software-based MDs per PPB Kenya MDSW guideline
Botswana	Jun 10	Notice	New combined registration process (screening + evaluation merged); effective July 1	P0	Registration	Submission Dossier	Submit pending applications by June 30; resubmit under new process post-July 1
China	Jun 1	Notification	NMPA Announcement 52/2026 — classification adjustment procedures; non-compliant products prohibited	P0	Registration	Technical File / Registration	Verify classification status; ensure compliant registration before transition deadline
Korea	Jun 10	Guidance	Labeling guideline for digital MDs — serial numbers, manufacturing dates, software versions	P0	Labeling	Labeling & IFU	Update digital MD labeling to include required software-specific information
Brazil	Jun 12	Circular	ANVISA DUIMP importation system — support measures for transition inconsistencies	P1	Import/Export	Import/Export	Review DUIMP product catalog submissions; correct inconsistencies per ANVISA guidance
EU	Jun 17	Guidance	MDCG guidance on standardization for medical devices (updated)	P2	Registration	Technical File	Review updated harmonized standards guidance for applicable devices
EU	Jun 18	Guidance	MDCG Position Paper 2026-4 — SS(C)P management in EUDAMED post-mandatory use	P0	Registration	Registration / Technical File	Ensure SSCP/SC documents are correctly managed in EUDAMED
Sweden	Jun 17	News	Swedish MPA designated as national CA for AI systems in MDs (EU AI Regulation)	P2	Software (SaMD/AI)	Technical File / Software	Assess AI Regulation obligations for AI-based MDs sold in Sweden
Korea	Jun 23	Enforcement Decree	Medical Device Act Enforcement Decree — conformity assessment; Regional FDAs can revoke; effective July 1	P0	Registration	Technical File / Registration	Ensure conformity assessment compliance; assess risk of revocation
Switzerland	Jun 19	Notification	Swissmedic fee ordinance — registration fees introduced from July 1	P0	Registration	Registration	Budget for new Swissmedic registration fees from July 1, 2026
Switzerland	Jun 19	Notification	New Swissdamed product registration options — online editor, M2M interface, Master UDI-DI	P0	UDI/Traceability	UDI / Registration	Use new Swissdamed tools to register products and manage UDI
Australia	Jun 22–24	Notifications	UDI newsletter; compliance timeframes v2.1; Consent to Supply process for UDI	P1	UDI/Traceability	UDI / Labeling	Align with updated UDI timeframes; follow Consent to Supply process
Mexico	Jun 17	Guidance	Cofepris guide for registration via Equivalence Agreements and Expedited Pathway	P1	Registration	Submission Dossier	Use updated guide for equivalence-based and expedited registration in Mexico
Canada	Jun 17	Bulletin	Medical Device Establishment Licensing Phase 2 — effective December 14, 2026	P1	Registration	Registration	Prepare for MDEL modernization; review establishment licensing requirements

Country	Date	Type	Title	Pri.	Domain	Dossier Sections	Action Required
Belarus	Jun 16	Notification	MD regulatory functions transfer to Gospharmnadzor from July 1, 2026	P0	Registration	Registration	Direct all Belarus MD regulatory contacts and submissions to Gospharmnadzor
Rwanda	Jun 18	Regulation	New GMP regulations for medical products	P1	QMS/GMP	QMS / Registration	Align GMP documentation with new Rwanda GMP regulatory framework
EU	Jun 22	Guidance	MDCG Position Paper 2026-5 — UDI assignment between manufacturers and distributors	P1	UDI/Traceability	UDI / Traceability	Clarify UDI assignment responsibilities with distribution partners
Portugal	Jul 19	News	Two EU delegated regulations on Well-Established Technologies (WET) enter into force	P0	Registration	Technical File / Registration	Verify applicability to WET devices; align technical dossier if applicable
South Africa	Jun 25	Guidance	RUO/IUO MD regulatory requirements and classification — SAHPRA guidance	P2	Registration	Technical File / Registration	Review and classify any RUO/IUO products per SAHPRA requirements
Botswana	Jun 18	Announcement	BoMRA MD listing database published; full regulatory controls incoming	P1	Registration	Registration	Submit for listing in BoMRA database; prepare for vigilance and import/export compliance
Kyrgyzstan	Jun 29	Resolution	Resolution 450 — Inspection Procedure for MD Circulation; QMS per EAEU standards	P0	QMS/GMP	QMS / Registration	Comply with new inspection procedure; ensure QMS is EAEU-aligned
Bahrain	Jul 14	Circular	MD registration extension + 10%/month quotas; catalogue by July 31; final deadline Apr/Jul 2027	P0	Registration	Registration	Submit complete unregistered device catalogue by July 31; plan monthly registration quotas
Saudi Arabia	Jul 8	Guidance	MDS-G029 — Risk Communication framework for MDs	P1	PMS/Vigilance	PMS / Vigilance	Implement risk communication framework; update PMS SOPs for Saudi Arabia
Egypt	Jul 15	Guidance	Egyptian guidance for adverse reaction detection and reporting for MDs 2026	P0	PMS/Vigilance	PMS / Vigilance	Implement updated adverse reaction reporting procedures for Egypt
Norway	Jul 15	Draft	Proposed amendment — EUDAMED mandatory for Norway; repeal of Articles 24–25	P3	Registration	Registration / UDI	Monitor; prepare for mandatory EUDAMED registration in Norway
Brazil	Jul 16	Notice	WHO interim MD regulatory authority list — ANVISA recognized (5 years)	P3	Registration	Submission Dossier	Informational; confirms ANVISA's international standing for reliance submissions
Canada	Jul 17	Notice	Expectations for Class III/IV MD licence application information — Notice to Industry	P1	Registration	Technical File / Submission Dossier	Review and align Class III/IV dossier content with updated Health Canada expectations
Sri Lanka	Jul 20	Notification	Submit copy of issued SIL to MDRD for dossier processing	P0	Registration	Submission Dossier	Submit SIL copy to MDRD to advance registration dossier processing
Oman	Jul 20	Regulation	Medical Device Reporting Form published by Ministry of Health	P0	PMS/Vigilance	PMS / Vigilance	Use new official form for all MD adverse event/complaint reporting in Oman
Oman	Jul 23	Regulation	Guideline on MD Reporting — adverse events and complaints in Oman	P0	PMS/Vigilance	PMS / Vigilance	Implement Oman MD reporting guideline; update PMS SOPs for Oman market
Egypt	Jul 20	Notification	EDA updated submission forms link launched	P0	Registration	Submission Dossier	Use updated EDA forms for all submissions
Ethiopia	Jul 20	Guideline	FSCA guideline — non-recall field safety corrective actions	P1	PMS/Vigilance	PMS / Vigilance	Implement FSCA procedures for Ethiopian market; update PMS processes
Ethiopia	Jul 20	Guideline	Medical Device Vigilance Guideline — adverse events reporting for Ethiopian market	P1	PMS/Vigilance	PMS / Vigilance	Establish adverse event reporting procedures for Ethiopian market
Latvia	Jul 20	News	Amendments to MD Regulation published	P2	Registration	Technical File / Registration	Review Latvia regulation amendments; assess impact on existing registrations
Saudi Arabia	Jul 21	Guidance	MDS-REQ8 — SFDA approval for MD advertising and charitable campaigns	P1	Registration	Labeling & IFU	Obtain SFDA approval before any MD advertising or promotional campaigns

Country	Date	Type	Title	Pri.	Domain	Dossier Sections	Action Required
UK	Jul 21	Guidance	MHRA register MD guidance — clarification on devices put into service only	P2	Registration	Registration	Review registration requirements for devices put into service in Great Britain
UK	Jul 21	Guidance	Custom-Made MD in Great Britain — registration requirements clarified	P2	Registration	Technical File / Registration	Ensure custom-made device registration complies with updated MHRA requirements
India	Jul 22	Guideline	Medical Device Software (MDSW) guidance under MDR 2017 — CDSCO	P1	Software (SaMD/AI)	Technical File / Software	Classify and document MDSW per CDSCO guidance; align software lifecycle documentation
Pakistan	Jul 22	Draft	Draft MD Refurbishment Regulations 2026 — 7-day comment period	P3	Registration	Technical File / Registration	Submit comments within 7 days if applicable; monitor for final rules
China	Jul 22	Guidance	NMPA releases 57 MD registration review guidelines across 14 categories	P1	Registration	Technical File / Clinical Eval	Review all 57 guidelines for applicable device categories; update dossiers accordingly
Brazil	Jul 22	Regulation	CONAMA Resolution 516 — hazardous substance restrictions in electrical/electronic equipment	P1	Technical File	Technical File	Assess RoHS-like compliance for electronic MDs sold in Brazil; update technical file
Argentina	Jul 22	Provision	ANMAT Provision 4550/2026 — criminal record certificate required for technical directors	P0	Registration	Registration	Obtain and submit criminal record certificates for technical directors and governing body members
Italy	Jul 23	Circular	Operational instructions for complaint reporting to Italian Ministry of Health	P0	PMS/Vigilance	PMS / Vigilance	Implement harmonized complaint reporting to Italian Ministry of Health
UK	Jul 24	Guidance	Clinical Investigations Submission — IEC 62304, labelling, essential requirements updated	P1	Clinical Trials	Clinical Trials / Technical File	Update clinical investigation submissions with IEC 62304 and updated risk analysis guidance
Tunisia	Jul 25	Notice	New APE import control procedure — dossier preparation recommendations	P1	Import/Export	Import/Export / Submission Dossier	Prepare structured APE submission dossiers per ANMPS checklist
South Africa	Jul 25	Form	Application to import Section 21 RUO MD including IVDs — new form	P1	Registration	Submission Dossier	Use new SAHPRA form for all RUO/IUO import applications
Egypt	Jul 27	Regulations	6 updated EDA clinical study forms (progress report, safety, authorization, CAPA templates)	P0	Clinical Trials	Clinical Trials	Use all 6 updated EDA clinical study forms for submissions in Egypt
Malaysia	Jul 27	Notification	Product classification fully online from August 1, 2026	P0	Registration	Submission Dossier	Submit all product classification applications online from August 1
EU	Jul 27	Guidance	MDCG Position Paper 2026-5 — UDI assignment between manufacturers and distributors	P1	UDI/Traceability	UDI / Traceability	Clarify contractual UDI responsibilities with distributors; update agreements
China	Jul 24	Standard	NMPA amendments to 4 industry standards (ultrasonic therapy, dental, bioburden, air-polishing)	P2	Registration	Technical File	Review applicable standard amendments; verify continued compliance
China	Jul 27	Draft	Draft measures for supervision of online sales of MDs; consultation until Aug 26	P3	Registration	Registration	Monitor; may impact online distribution strategy for China
China	Jul 24	Draft	3 draft UDI technical guidance documents; consultation until Aug 23	P3	UDI/Traceability	UDI / Traceability	Participate in consultation; monitor for UDI implementation impacts in China
Ethiopia	Jul 29	Guidelines (13)	EFDA comprehensive framework: SaMD/AI, IVD classification, labeling, GMP, marketing authorization, post-approval changes, bundling, borderline devices	P1	Registration	Technical File / Clinical Eval / Labeling / QMS / Software	Full dossier review for Ethiopia market entry; align with all 13 new EFDA guidelines
Yemen	Jul 28	Notice	SBDMA new website launched with guidelines and services	P3	Registration	Submission Dossier	Consult new SBDMA website for Yemen regulatory services
Belarus	Jul 22	Draft	Draft to reduce timeframe for preliminary technical work on MD registrations	P3	Registration	Registration	Monitor; could accelerate Belarus registration timelines

✓ Consolidated Dossier Action Checklist

🔴 Technical File / Design Dossier

- China: Review 57 new NMPA registration review guidelines (Jul 2026)
- China: Apply 5 new Class III cardiovascular device guidelines (May 2026)
- China: Review 4 standard amendments (ultrasonic, dental, bioburden, air-polishing)
- EU: Apply notified body requirements from Implementing Regulation 2026/977
- EU: Manage SSCP/SC documents in EUDAMED per MDCG 2026-4
- EU: Review WET delegated regulations for applicable devices (Jul 2026)
- India: Classify and document MDSW per CDSCO software guidance
- Ethiopia: Full technical dossier review for Ethiopia market entry (13 EFDA guidelines)
- Brazil: Assess hazardous substance compliance (CONAMA Resolution 516)
- Korea: Update digital MD labeling (serial numbers, dates, software version)

🟡 Clinical Evaluation Report (CER/PER)

- China: Align CER with 5 new Class III cardiovascular device guidelines
- China: Update clinical evaluation for applicable guidelines across 57 published (Jul 2026)
- UK: Update clinical investigation submissions per IEC 62304, labeling, risk analysis
- Korea: Leverage RWE pathway; remove notarization for foreign clinical data

🔑 Labeling & IFU

- Algeria: Review labeling/packaging against Note 42 requirements
- Egypt: Align labeling with UDI requirements per EDA guidance
- South Africa: Implement e-IFU per SAHPRA requirements
- Korea: Update digital MD labeling with software-specific information
- Ethiopia: Align labeling with EFDA labeling guideline
- Saudi Arabia: Obtain SFDA pre-approval for any advertising materials

📌 UDI / Traceability

- EU/EUDAMED: Register all economic operators and devices (mandatory since May 28)
- Switzerland: Register in Swissdamed + manage UDI via new tools (July 1 fees apply)
- Bahrain: Register in TATABU; complete by July 31; MADAR 2.0 for all services
- Turkey: Align ÜTS with EUDAMED; update device registrations
- Australia: Submit UDI records to AusUDID; follow Consent to Supply process
- Egypt: Implement EDA UDI requirements for devices and IVDs
- EU (MDCG 2026-5): Clarify UDI assignment responsibilities with distributors

💻 Software (SaMD / AI)

- Kenya: Register software-based MDs per PPB Kenya MDSW guideline

⚙️ Quality Management System (QMS/GMP)

- Uzbekistan: Ensure ISO 13485 documentation ready for registration inspection
- Kyrgyzstan: Comply with new MD inspection procedure (EAEU-aligned QMS)
- Rwanda: Align GMP documentation with new Rwanda GMP regulation
- Brazil: Participate in IMDRF supplier quality control consultation (July 6)
- Algeria: Review GDP/GPP compliance for supply chain activities
- Ethiopia: Align with EFDA GMP guideline

📊 Post-Market Surveillance (PMS/Vigilance)

- EU/Finland: Implement new MIR form v7.3.1 for serious incident reporting
- Switzerland: Follow Swissmedic incident report guideline for CH submissions
- Saudi Arabia: Implement Risk Communication framework (MDS-G029)
- Oman: Use new MD Reporting Form and Reporting Guideline
- Egypt: Implement updated adverse reaction reporting guideline
- Ethiopia: Establish vigilance and FSCA procedures per EFDA guidelines
- Italy: Follow operational instructions for complaint reporting to Italian Ministry
- Spain: Review vigilance responsibilities in healthcare centers (AEMPS update)

📋 Registration / Marketing Authorization

- EU: Complete EUDAMED registration (mandatory May 28)
- Germany: No longer use DMIDS — all registrations in EUDAMED
- Switzerland: Register in Swissdamed + pay new registration fees from July 1
- Bahrain: Transition to MADAR 2.0; submit device catalogue by July 31
- Belarus: Redirect all regulatory submissions to Gospharmnadzor (from July 1)
- Argentina: Submit criminal record certificates for technical directors
- Korea: Comply with Enforcement Decree conformity assessment system (July 1)
- Botswana: Submit listing applications; prepare for full regulatory controls
- Ecuador: Plan dossier alignment with new ARCSA regulation (enforcement Jan 2027)
- Malaysia: Use fully online product classification from August 1

🔬 Clinical Trials / Performance Studies

- Chile: Align clinical trial protocols with new GCP guidelines (Resolution 2050/2026)
- Egypt: Use all 6 updated EDA clinical study forms
- Mexico: Use updated COFEPRIS research protocol submission procedures
- UK: Update clinical investigation submissions (IEC 62304, risk analysis)
- Korea: Leverage RWE pathway; no notarization for foreign translations

- India: Classify and document MDSW under CDSCO guidance
- Sweden: Assess EU AI Regulation obligations for AI-based MDs
- Ethiopia: Align SaMD/AI products with EFDA SaMD/AI guideline

 Import/Export / Distribution

- Iraq: Book all registration visits online (mandatory)
- Lebanon: Submit non-implantable import invoices via MEDIMPORT (by Aug 9)
- Lebanon: Remove unused FDA-approved implantables via MEDTRACE
- Nicaragua: Use new MINSA import/export form
- Guyana: Use GESW portal for all import/export regulatory permits
- Tunisia: Prepare structured APE dossiers per ANMPS checklist
- Oman: Ensure establishment approval before requesting device clearance

 Submission Dossier / eSTAR

- USA: Update eSTAR with Human Factors content — enforcement August 1
- Canada: Use REP for all MD submissions (mandatory)
- Canada: Align Class III/IV dossier with updated Health Canada expectations
- Mexico: Review Cofepris requirements per new streamlining agreement
- Saudi Arabia: Apply bundling guidance (MDS-G028) for multi-device MDMA submissions

Priority Legend

-  **P0** — Already in force; immediate dossier action required
-  **P1** — Enforcement within 3 months; urgent planning needed
-  **P2** — Enforcement 3–6 months out; planning phase
-  **P3** — Watch list: drafts, guidance updates, no immediate deadline