ARAZY GROUP
MedTech Regulatory Technology

REPORT DATE
July 26, 2026

COVERAGE WINDOW
June 27 – July 26, 2026

REG Talks

Global Regulatory Information Digest

Monthly

TABLE OF CONTENTS

This Month's Synthesis

Month-specific patterns observed in scope-filtered items. Distinct from durable Macro-Trends below.

■ July 1 was a synchronized global compliance date. Australia UDI Class III/IIb, Switzerland Swissdamed, Germany BfArM DiGA AbEM data collection, South Korea MFDS cybersecurity mandatory-effect, and Malaysia-China Joint Evaluation Phase 2 all took effect on the same date. This is now the largest single-day accumulation of medical-device compliance obligations of the year.

■ The 30-day window closed with three carryover verification items resolved and one still pending. OJEU publication of the EU AI Act Digital Omnibus, the correct ANVISA IFU resolution number (RE 2.435/2026), and the MFDS Korea standards-package notice number (2025-45) all resolved definitively; the India CDSCO G.S.R. 515(E) and 269(E)/270(E) drafts remain in Draft Notification status for a third consecutive run.

■ EU framework tightening continued on multiple parallel fronts. MDCG 2026-4 SSCP/SSP Playground live; EUDAMED four modules operational; NB timeline-cap regulation in force; Team-NB position papers advancing on risk-adaptive surveillance and IVDR transfer agreements; and the AI Act Digital Omnibus published in OJEU. The peak-preparation window ahead of the February 2027 SS(C)P legacy-upload deadline is now H2 2026.

■ Cluster enforcement escalation is the single loudest US signal. The convenience-kit cluster grew from 3 linked classifications (Run #11) to 9 linked classifications (Run #12) in the same supply chain and same 30-day window - materially outpacing the multi-run baseline for individual recalls and warning letters. Attribution now points upstream to recalled BD ChloraPrep/FREPP applicator components. Kit assemblers sourcing these applicators should assume audit exposure.

■ Asia-Pacific regulators moved on modernization in a coordinated wave without a coordinating body. China (Solicita mandatory), Taiwan (e-submission + AI GMLP + fee consultation), Malaysia (China joint evaluation Phase 2, Thailand reliance full implementation), and Korea (MFDS Notice 2025-45, cybersecurity mandatory-effect, digital-device waiver expansion, testing-body simplification) each independently advanced digitization or reliance programs. Manufacturers pursuing multi-market APAC strategies can now compound benefits from parallel administrative-modernization tracks.

REGULATORY INTELLIGENCE SPOTLIGHT

EU AI Act Digital Omnibus published in OJEU as Regulation (EU) 2026/1744

The Digital Omnibus on AI was adopted July 8 and published in the Official Journal of the EU on July 24, 2026 as Regulation (EU) 2026/1744, resolving the multi-run "pending publication" watch item. The regulation integrates AI Act high-risk obligations directly into the existing MDR/IVDR conformity-assessment framework rather than creating a duplicate track for medical devices. Key staggered dates: watermarking obligations from December 2, 2026; Annex III high-risk systems from December 2, 2027; Annex I product-embedded systems (including medical devices as safety components) from August 2, 2028; regulatory sandboxes from August 2, 2027. Enters into force July 27, 2026. Confirmed via Council document PE-CONS 30/26, *DLA Piper analysis*, and *Law & Technology commentary*. Direct EUR-Lex fetch failed (robots-block) during compilation and should be re-verified next run.

Global UDI / registration-database enforcement reaches simultaneous critical mass on July 1

Three unrelated regulators activated hard-deadline registration-database or UDI compliance obligations on the same date: Australia TGA UDI mandatory for Class III and Class IIb devices, Switzerland Swissdamed mandatory registration for all devices/IVDs/systems (with no grace period for vigilance-event-linked devices), and the EU's EUDAMED four-module mandatory-use regime (Actor Registration, UDI/Devices, Notified Bodies & Certificates, Market Surveillance) continued in force alongside a looming legacy-device UDI data deadline of November 28, 2026. Multi-market manufacturers now face compounding administrative burden precisely because these deadlines cluster in the same month across systems that do not coordinate. Confirmed via TGA UDI news, *Swissmedic guidance*, and *MedTech Europe EUDAMED milestone*.

AI/ML SaMD governance is consolidating into existing device frameworks - not parallel regimes

A jurisdiction-agnostic pattern crystallized this month: rather than build standalone AI-device laws, regulators are folding AI/ML obligations into established medical-device frameworks. Evidence points across regions: the EU integrates AI Act high-risk obligations into MDR/IVDR conformity assessment; South Korea MFDS proposed expanding the digital-medical-device clinical-data waiver to all device classes via *Public Notice 2026-322* and simplified testing-body designation; Taiwan TFDA published IMDRF-aligned *Good Machine Learning Practice guidance* for AI-enabled devices; ISO published *ISO/TS 24971-2:2026* AI/ML risk-management guidance under the existing ISO 14971 umbrella (excluding LLMs and generative AI). Manufacturers should therefore expect AI-specific requirements to arrive as amendments to systems they already implement, not as new certification tracks.

Regulatory Intelligence Detail

Coverage window: June 27 - July 26, 2026. Mode: Monthly. Items below are tagged CRITICAL (framework-level or policy-triggering) or STRATEGIC (durable regulatory impact). All scope-filtered to medical devices, IVDs, SaMD, drug-device combinations.

European Union

GENERAL

CRITICAL EU AI Act Digital Omnibus - Regulation (EU) 2026/1744 published in OJEU

Adopted 2026-07-08; published OJEU 2026-07-24; enters into force 2026-07-27

The Digital Omnibus on AI was formally adopted July 8 and published in the Official Journal of the EU on July 24, 2026 as *Regulation (EU) 2026/1744*, entering into force July 27, 2026. It integrates AI Act high-risk requirements into the existing MDR/IVDR conformity-assessment framework. Staggered dates: watermarking December 2, 2026; Annex III high-risk December 2, 2027; Annex I product-embedded systems (including medical devices as safety components) August 2, 2028; regulatory sandboxes August 2, 2027. Confirmed via Council PE-CONS 30/26 and *DLA Piper analysis*.

> Why this matters: This is the single most consequential AI/MedTech convergence event of the month. Medical-device manufacturers building AI/ML-enabled SaMD now have a confirmed August 2028 runway before AI Act obligations bind on top of MDR/IVDR - but should begin integrated gap-assessment now given the shared-not-parallel compliance model. EUR-Lex entry now confirmed: Regulation (EU) 2026/1744 on EUR-Lex.

CRITICAL MDCG 2026-4 EUDAMED SSCP/SSP Playground confirmed live in July 2026

Deployment planned in July 2026; production October 2026; upload deadline 2027-02-27

MDCG 2026-4 confirms the SSCP/SSP Playground test environment deployment for July 2026 ahead of full production in October 2026. Manufacturers must upload SS(C)Ps no later than February 27, 2027; the NB certificate-registration transition ends May 27, 2027. Exact day-level Playground go-live date within July was not found in-window and remains a factcheck item.

> Why this matters: The Playground gives manufacturers a live sandbox to validate SSCP/SSP data structures nearly seven months ahead of the hard February 2027 upload deadline. Early engagement reduces risk of a compressed late-2026 scramble.

CRITICAL EUDAMED first four modules - mandatory use continues; legacy UDI deadline approaching

Mandatory since 2026-05-28; legacy UDI data deadline 2026-11-28

Mandatory use of EUDAMED's first four modules (Actor Registration, UDI/Devices, Notified Bodies & Certificates, Market Surveillance) began *May 28, 2026 per MedTech Europe* and remained the operational baseline throughout this window. Legacy-device UDI/Device data submission is due November 28, 2026; the NB/Certificates module transition runs to May 27, 2027. *HPRA guidance* reiterates the operational obligations.

> Why this matters: With legacy UDI/Device data due in four months, manufacturers who have not yet completed legacy-device data migration face a compressed timeline into Q4 2026.

STRATEGIC Implementing Regulation (EU) 2026/977 - Notified Body timeline caps and pricing transparency

Adopted 2026-05-04; industry digestion continues through window

Implementing Regulation (EU) 2026/977 caps Notified Body conformity-assessment timelines (30 days for application review, 120 days for QMS audit) and mandates standardized pricing transparency across NBs. Coverage via *Nelson Advisors European MedTech weekly (3 July 2026)*, corroborated in the *17 July 2026 edition*. Primary source: Implementing Regulation (EU) 2026/977 on EUR-Lex.

> Why this matters: Predictable capped NB review timelines materially improve manufacturers' ability to forecast MDR/IVDR certification schedules - addressing a long-standing industry pain point without assuming NB capacity growth.

STRATEGIC Team-NB position paper list update - risk-adaptive surveillance and IVDR transfer agreements

2026-07-15

Team-NB updated its position paper list on 2026-07-15, including active papers on the MDR Certification Process V2.1, risk-adaptive surveillance proposals under MDR/IVDR, Micro/Small Enterprise initiatives, and IVDR transfer-agreement guidance.

> Why this matters: Team-NB position papers often anticipate or shape subsequent MDCG guidance; the risk-adaptive surveillance and IVDR transfer papers are especially relevant for manufacturers planning NB transitions in H2 2026.

STRATEGIC MedTech Europe - combined MDSAP/MDR/IVDR audit call and June headlines

2026-07-02

MedTech Europe issued a *call to manufacturers* encouraging European regulator observation of combined MDSAP/MDR/IVDR audits, alongside its *June 2026 headlines recap* which flagged an IVDR position paper and reported Notified Body staff reductions.

> Why this matters: Combined-audit advocacy reflects industry pressure to reduce duplicative audit burden as MDSAP and EU frameworks overlap; NB staffing reductions are a signal worth monitoring for capacity/timeline impact through H2 2026.

MONITOR Harmonised Standards - Commission Implementing Decision (EU) 2026/1231

2026-06-11 (predates window; digestion continues)

The most recent Commission Implementing Decision adding harmonised-standards references under MDR/IVDR is Decision (EU) 2026/1231 of June 11, 2026 per the Commission harmonised-standards page.

> Why this matters: Harmonised-standard listings determine which standards confer presumption of conformity; manufacturers should confirm their applied standards versions match the latest OJEU list.

United Kingdom

GENERAL

CRITICAL MHRA Annual Fee deadline - July 31, 2026

Deadline 2026-07-31

MHRA confirmed the annual device registration fee (£300 per GMDN Level 2 category under the fee structure effective April 1, 2026) remains due July 31, 2026, with no further extension identified. Details in the MHRA placing-on-market guidance PDF.

> Why this matters: All UK device registrants must complete payment by this date to remain compliant. This is the most time-sensitive UK deadline of the reporting period - falling five days after this digest publishes.

STRATEGIC MHRA Draft Medical Devices (Amendment) Regulations 2026 - WTO comment period closed

WTO comments closed 2026-07-07; parliamentary laying expected Q4 2026

The WTO TBT comment period on MHRA's draft Medical Devices (Amendment) Regulations 2026 closed July 7, 2026 per *BHTA analysis* and *Emergo by UL*. Expected timeline: Parliamentary laying Q4 2026, in-force for GB market Spring 2027, international-reliance pathways Q2-Q3 2028.

> Why this matters: This draft statutory instrument represents the next major evolution of the UK post-Brexit device framework. Manufacturers planning multi-year UK market strategies should track Parliamentary progress closely.

STRATEGIC MHRA secures fraud convictions – falsely marked P900 enteral feeding pumps

Convictions 2026-07-01; sentencing 2026-09-23 (Harrison only; Medicina Ltd date TBD)

MHRA secured criminal convictions following a decade-long investigation into Kenneth George Harrison and Medicina Ltd for falsely marked P900 enteral feeding pumps, with sentencing for Kenneth George Harrison set for September 23, 2026 (a sentencing date for Medicina Ltd is yet to be fixed). See the GOV.UK news release.

Why this matters: This is MHRA's highest-profile criminal enforcement outcome of the month, signaling continued willingness to pursue multi-year fraud investigations against device counterfeiting/false-marking schemes.

MONITOR MHRA Field Safety Notice batches – two batches this window

Batch 1: Jun 29–Jul 3 (published Jul 7); Batch 2: Jul 13–17 (published Jul 21)

MHRA published FSN batch for 29 June – 3 July 2026 (bioMerieux ARGENE ENTEROVIRUS, Boston Scientific Rapid Refill, Chalice Medical ECLS Tubing, Corin TaperFit, Maquet Flow-i, Philips, WEINMANN MEDUMAT) and a second batch for July 13–17, 2026 (Philips Allura Xper FD10, ICL/TICL Calculator/IOD Software, hospital beds, imaging/monitoring devices).

Why this matters: The Allura Xper FD10 also appears in Health Canada's recall list in the same window, evidencing coordinated multi-market notification by the manufacturer.

Switzerland

GENERAL

CRITICAL Swissdamed mandatory device registration – effective July 1, 2026

Effective 2026-07-01; transition ends 2026-12-31 for existing devices

Registration in the Swissdamed database became mandatory July 1, 2026 for all medical devices, IVDs, systems/procedure packs and MD-DEVIT products placed on the Swiss market per *Swissmedic guidance*, corroborated by *Walder Wyss legal alert*. A transition period to December 31, 2026 applies to devices already on the market, but no grace period applies to devices linked to vigilance events – those must be registered immediately. Fees: CHF 200 for the first device plus CHF 20 per additional device, capped at CHF 10,000 per manufacturer per year, first invoicing January 2027.

Why this matters: This is a hard compliance deadline affecting every device on the Swiss market. Companies with open vigilance events must register immediately, making this the most time-critical Swiss item of the month.

Germany

GENERAL

STRATEGIC BfArM DiGA mandatory AbEM data collection begins

Effective 2026-07-01; first report due 2027-04-15

Digital health app (DiGA) manufacturers are now required to collect application-accompanying success measurement (AbEM) data starting with Q3/Q4 2026, with the first formal report due April 15, 2027. See the *BfArM DiGA/DiPA overview*.

Why this matters: This shifts DiGA manufacturers from a listing-only obligation to an active real-world-evidence generation requirement, with implications for how digital therapeutics demonstrate ongoing clinical value.

Ireland

GENERAL

STRATEGIC HPRA to support Ireland's EU Council Presidency (Jul-Dec 2026)

Announced 2026-07-15

HPRA announced it will support Ireland's EU Council Presidency (July-December 2026) by hosting approximately 25 meetings addressing MDR/IVDR revision and the proposed Biotech Act - see the *HPRA news release*.

> Why this matters: Ireland's Presidency term positions HPRA as a convening hub for MDR/IVDR revision discussions through year-end, making Irish-hosted meeting outputs a leading indicator of forthcoming EU-level framework changes.

MONITOR HPRA Field Safety Notices summary - June 2026

Published 2026-07-03

HPRA published its *June 2026 FSN summary*, including a Baxter Homechoice PD Set FSN and an Automated Impella Controller FSN dated July 1, 2026.

> Why this matters: The Impella-related FSN aligns with the broader Impella recall activity also seen at FDA this month, suggesting a coordinated global field action by the manufacturer.

United States

GENERAL

CRITICAL FDA Human Factors final guidance - eSTAR HF Submission Category required from August 1, 2026

Town Hall held 2026-07-22; eSTAR HF-category declaration required from 2026-08-01

CDRH held its Town Hall on the Human Factors Content of Marketing Submissions final guidance on July 22, 2026, immediately ahead of August 1, 2026, when revised eSTAR templates begin requiring an HF Submission Category declaration per the FDA Human Factors final guidance (finalized May 29, 2026, FR Doc 2026-10734). The guidance itself is nonbinding; the operative change is the eSTAR template requirement.

> Why this matters: All pending 510(k)/PMA/De Novo submissions with human factors content must be aligned against the new guidance and prepared to declare the HF Submission Category in eSTAR from August 1 onward. The eSTAR change falls five days after this digest publishes.

STRATEGIC CDRH Laser Safety Guidance revision - new 5-day filing requirement

2026-07-13

CDRH issued a revised Laser Safety Guidance introducing a new 5-day filing requirement and aligning with IEC 60825-1:2024 Annex D.3 per FDA CDRH News.

> Why this matters: Manufacturers of laser-containing medical devices face a materially shorter compliance-filing window and a new international standard reference that should be incorporated into design-history files immediately.

STRATEGIC MDUFA reauthorization draft commitments letter published

Published 2026-07-07; public meeting 2026-08-05; comments due 2026-08-07

FDA released its draft commitments letter for the Medical Device User Fee Amendments (MDUFA) reauthorization cycle via Federal Register notice, with an upcoming public meeting on August 5, 2026 and comment deadline August 7, 2026 per *Holland & Knight analysis*.

> Why this matters: MDUFA commitments shape review-timeline performance goals and fee structures for years; industry should submit comments before the August 7 deadline to influence final terms.

MONITOR Federal Register: Voluntary Improvement Program notice and ASCA information collection

VIP FR Doc 2026-14436 published 2026-07-17; ASCA comments due 2026-09-15

FDA published a Federal Register notice regarding its Medical Device Voluntary Improvement Program (FR Doc 2026-14436), and separately opened an information-collection comment period for the Accreditation Scheme for Conformity Assessment (ASCA) with a September 15, 2026 deadline. Access via Federal Register.

> Why this matters: ASCA's continued information-collection renewal signals the program remains active and evolving; manufacturers using ASCA-accredited testing labs should track potential procedural changes.

DEVICE-SPECIFIC

STRATEGIC Convenience-kit component recall cluster - 9 linked classifications

Posted 2026-07-23 (Z-2779-2026 through Z-2787-2026); Early Alerts 2026-07-09

FDA posted a cluster of nine related recall classifications (Z-2779-2026 through Z-2787-2026) covering convenience kits (including Foley catheter trays), continuing the multi-firm convenience-kit quality issue pattern first observed in Run #11. FDA's July 9 Early Alert attributes the underlying defect to recalled BD ChloraPrep 1 mL / FREPP 1.5 mL applicator components included in the kits (a BD drug recall for potential sterile-barrier breach due to defective paper lidding), sourced via the FDA Medical Device Recalls Database.

> Why this matters: Nine linked classifications posted the same week is a strong clustering signal reflecting a single upstream BD applicator recall propagating through multiple convenience-kit assemblers. Kit assemblers incorporating the recalled BD ChloraPrep/FREPP applicator components should quarantine affected lots, apply Medline's over-labels, and expect additional linked classifications in H2 2026.

MONITOR Class I recalls - Insulet Omnipod and Abiomed Impella CP (1 death)

2026-07-02

FDA classified two Class I recalls on the same day: Insulet's Omnipod insulin management system and Abiomed's Impella CP heart pump, the latter associated with at least one patient death per the FDA recalls page.

> Why this matters: Two Class I recalls (highest severity) on the same date across different device categories represent the most severe individual safety actions of the window and warrant field-action monitoring by adjacent-technology manufacturers.

MONITOR Corrections - Fresenius Kabi, Hologic, Draeger, GE HealthCare

GE 2026-06-22; Hologic and Draeger 2026-06-30; Fresenius Kabi 2026-07-07

Four separate device corrections were posted across the window: Fresenius Kabi Ivenix infusion pump, Hologic BioZorb tissue marker, Draeger Atlan anesthesia workstation, and GE HealthCare Giraffe/Panda infant warmers/incubators - via the FDA recalls and Early Alerts page.

> Why this matters: Distributed across unrelated device categories (infusion, oncology marker, anesthesia, neonatal warming), these corrections indicate routine field-action cadence rather than a systemic issue.

COMPANY-SPECIFIC

MONITOR Warning letters batch - BlephEx, Skytron, Nihon Kohden, ZIIP, Happiest Baby/SNOO, Medline/NAMIC

Posted across window (Jul 07, Jul 14, Jul 04 posted)

FDA posted a batch of warning letters covering: BlephEx and Skytron (unauthorized marketing, *RAPS coverage*); Nihon Kohden and ZIIP (adulterated/misbranded / QSR); Happiest Baby SNOO (unauthorized marketing + mold complaints, warning letter PDF); Medline NAMIC syringes/manifolds (QSR violations). Common landing page: FDA Warning Letters.

> Why this matters: Reinforces CDRH's continued dual enforcement focus on unauthorized marketing claims plus Quality System Regulation non-conformance - two of the most consistent enforcement themes. The Medline warning letter adds another data point to the broader Medline-adjacent quality scrutiny visible in the convenience-kit cluster.

MONITOR Bolton Medical Relay Pro stent graft - Dear Colleague letter update

2026-07-20

FDA issued a Dear Colleague letter update regarding the Bolton Medical Relay Pro stent graft system as part of a *regulatory update package*.

> Why this matters: Structural/vascular graft field actions typically carry long-tail follow-up (imaging surveillance recommendations); physicians and device makers with implanted patients should track further FDA communication.

Canada / Mexico

GENERAL

STRATEGIC COFEPRIS NOM-137-SSA1-2025 - continued digestion; enters force 2027-05-14

Published DOF 2026-05-19 (predates window); mandatory 2027-05-14

No new in-window COFEPRIS device-specific action was found beyond continued industry digestion of NOM-137-SSA1-2025, the device-labeling standard published in May 2026. Full text via *DOF PDF*.

> Why this matters: With a 2027-05-14 mandatory effective date and 180-day sell-through extending to November 2027, manufacturers selling into Mexico have a defined multi-quarter runway to update labeling but should begin transition planning now.

DEVICE-SPECIFIC

MONITOR Health Canada recalls - Astral 150 ventilator, Alice Le System Sleepware, Allura Xper FD10

Jul 08 (Alice Le, Allura Xper); Jul 09 (Astral 150)

Health Canada posted recalls for the ResMed Astral 150 ventilator, Philips Alice Le System Sleepware sleep-diagnostic software, and the Philips Allura Xper FD10 angiographic X-ray system via the Health Canada Recalls and Safety Alerts portal.

> Why this matters: Two of the three recalls (Alice Le, Allura Xper) mirror devices also flagged in UK MHRA FSN batches in the same window, suggesting coordinated multi-jurisdiction field actions by the manufacturer group.

China

GENERAL

STRATEGIC CMDE releases 57 registration review guidelines in single batch (Announcement 2026 No. 24)

2026-07-21

CMDE issued Announcement 2026 No. 24, releasing 57 registration review guidelines covering active devices, non-active surgical instruments, dental devices, and IVD reagents per *Hlongmed summary*.

Why this matters: A batch release of 57 guidelines is an unusually large single-day guidance drop, materially expanding the technical review framework manufacturers must reference for China registrations across multiple device categories.

MONITOR NMPA - Solicita system mandatory for certificate generation

Effective 2026-07-03

All medical device certificate generation moved exclusively to the Solicita electronic system starting July 3, 2026 per *regulatory summary*.

Why this matters: This is an operational/administrative digitization milestone that affects every registrant's certificate issuance workflow in China going forward.

MONITOR NMPA - Periodic Risk Assessment Report submission form revised

2026-07-09

NMPA revised the Periodic Risk Assessment Report submission form used for post-market safety reporting per *Asia Actual analysis*.

Why this matters: Registrants must update their post-market surveillance report templates to match the revised form ahead of their next periodic filing.

MONITOR NMPA Class II clinical trial exemption clarification

Within window (exact date not isolated)

NMPA issued clarification on clinical-trial exemption criteria for select Class II devices including blood glucose meters, blood pressure monitors, and ultrasound systems per *VCBeat coverage*. Exact publication date was not isolated in-window and is flagged in factcheck notes.

Why this matters: Expanded clinical-exemption clarity for these common device categories can shorten registration timelines for manufacturers of routine diagnostic/monitoring devices.

DEVICE-SPECIFIC

MONITOR NMPA innovative device approvals - implantable cardiac event monitor and intracranial stent

Jul 01 (cardiac monitor); Jul 02 (intracranial stent)

NMPA approved an implantable cardiac event monitor and an intracranial stent through its Innovative Device expedited pathway per *innovative device summary*.

Why this matters: Continued innovative-pathway approvals signal NMPA's ongoing prioritization of expedited review for novel cardiovascular and neurovascular devices.

Japan

GENERAL

MONITOR MHLW 2026 MDSAP Forum

Reported 2026-07-09

MHLW held its 2026 MDSAP Forum per MHLW announcement.

Why this matters: Continued MHLW engagement with MDSAP signals ongoing Japanese regulatory alignment with the multi-jurisdiction single-audit program.

South Korea

GENERAL

CRITICAL MFDS cybersecurity guidance - mandatory effective July 1, 2026

Issued 2026-03-12; mandatory effect 2026-07-01

MFDS's cybersecurity guidance for medical devices, issued March 12, 2026, became mandatory as of July 1, 2026 per *Leanabl regulatory update*.

Why this matters: All connected/networked medical devices entering the Korean market must now demonstrate compliance with this cybersecurity framework as a baseline requirement.

STRATEGIC MFDS Notice No. 2025-45 - standards package effective July 4, 2026

Effective 2026-07-04

MFDS Notice No. 2025-45 (medical device standards package) took effect July 4, 2026, resolving the multi-run notice-number tracking item. Official text via *law.go.kr*.

Why this matters: This confirms the specific standards package manufacturers must reference for Korean market conformity as of early July 2026.

STRATEGIC MFDS Public Notice No. 2026-322 - digital medical device clinical-data waiver expansion

Issued 2026-07-01; comment period closed 2026-07-21

MFDS proposed expanding the digital medical device clinical-data waiver to all device classes via Public Notice No. 2026-322, with the comment period closing July 21, 2026 per *CLARE Partners analysis*.

Why this matters: Expanding clinical-data waivers to all classes could materially accelerate Korean market entry for digital therapeutics and SaMD across the full risk spectrum.

MONITOR MFDS Notice No. 2026-282 - GMP amendment

Within window

MFDS issued Notice No. 2026-282, a partial amendment to medical device manufacturing and quality management standards (GMP) per TUV Rheinland summary.

Why this matters: GMP amendments directly affect manufacturer quality-system documentation and audit preparation for Korean-market devices.

MONITOR MFDS testing-body designation simplification for digital medical devices

2026-07-16

MFDS announced simplified certification/testing-body designation requirements specifically for digital medical devices per *Seoul Economic Daily*.

Why this matters: Reduces administrative friction for digital health manufacturers seeking Korean testing-body designation, complementing the clinical-data waiver expansion above.

MONITOR MFDS Notice 2026-31 - Class II streamlined notification

Effective July 2026

MFDS Notice 2026-31 streamlines the notification process for Class II devices per *Leanabl regulatory update*.

Why this matters: Streamlined Class II notification reduces administrative burden for the largest volume category of routine device registrations in Korea.

Taiwan

GENERAL

STRATEGIC TFDA - e-submissions live, AI GMLP guidance published, fee revision consultation open

Reported 2026-07-22; fee consultation open through 2026-08-28

TFDA is now accepting electronic submissions for low-risk Class I device registration via its Medical Device Premarket E-submission System, published IMDRF-aligned Good Machine Learning Practice guidance for AI-enabled devices, and MOHW proposed fee revisions with a consultation period open through August 28, 2026 per *Emergo by UL Taiwan market update*.

Why this matters: Three simultaneous developments - digitization, AI-specific guidance, and fee restructuring - represent a coordinated modernization push. The GMLP guidance is particularly relevant for AI/ML SaMD manufacturers as it aligns Taiwan with international IMDRF norms.

Australia

GENERAL

CRITICAL TGA UDI mandatory compliance - Class III and Class IIb devices

Effective 2026-07-01

TGA's Unique Device Identification (UDI) mandatory compliance requirement took effect July 1, 2026 for Class III and Class IIb devices per TGA UDI news. A streamlined UDI Consent to Supply process was introduced concurrently with reduced fees ($80 for first ARTG entry, $10 for additional entries).

Why this matters: Hard compliance deadline for the highest-risk device classes. Manufacturers without UDI compliance for Class III/IIb devices as of this date face market-access risk.

Malaysia / ASEAN

GENERAL

STRATEGIC Malaysia MDA - Thai FDA regulatory reliance programme - full implementation

Announced 2026-05-01 (predates window); full implementation status continues

MDA and Thai FDA's regulatory reliance programme moved to full implementation following its initial 3-month pilot per *MDA joint announcement*.

Why this matters: Regulatory reliance between these two ASEAN regulators reduces redundant review for manufacturers pursuing both markets - a model that may extend to other ASEAN members.

MONITOR Malaysia MDA - China Joint Evaluation Pilot Programme Phase 2

2026-07-01 through 2026-09-30

Phase 2 of the Malaysia-China Joint Evaluation Pilot Programme launched July 1, 2026 and runs through September 30, 2026 per the *MDA official portal*.

Why this matters: Continued joint-evaluation programs reduce duplicate review burden for manufacturers seeking both Malaysian and Chinese market access simultaneously.

India

GENERAL

MONITOR CDSCO G.S.R. 515(E) - remains in Draft Notification status

Draft published 2026-06-23; still Draft at window close

G.S.R. 515(E), the draft amendment to the Medical Devices Rules 2017 (compressing QMS review timelines - Rule 20(5) to 30 days, Rule 21(4) from 45 to 30 days, Rule 25(1) from 45 to 20 days), remains listed as a Draft Notification on the CDSCO Gazette Notifications page, not yet finalized as of this window's close. Corroborated by *koreamedglobal.com analysis*.

Why this matters: Manufacturers should not yet rely on the compressed review timelines as binding but should prepare for their likely eventual adoption given the draft's advanced stage. Would escalate to CRITICAL upon finalization.

MONITOR CDSCO G.S.R. 269(E)/270(E) - also remains Draft

Draft published 2026-04-10; unchanged through window

The related draft amendments G.S.R. 269(E)/270(E), addressing manufacturing-license timeline rationalization, also remain in Draft Notification status per *koreamedglobal.com analysis*.

Why this matters: Both major CDSCO timeline-reform drafts remain pending simultaneously, suggesting a coordinated future finalization rather than piecemeal rollout. Unresolved for three consecutive runs (Runs #10, #11, #12).

Brazil

GENERAL

CRITICAL ANVISA RE nº 2.435/2026 - correct resolution number confirmed for mandatory IFU upload

Published 2026-06-18

Resolucao-RE numero 2.435, de 18 de junho de 2026 is confirmed as the correct resolution establishing the mandatory 30-day Instructions for Use (IFU) upload requirement under RDC 751/2022 and RDC 830/2023 - resolving the resolution-number ambiguity (previously suspected as RE 2438/2026 or RE 2260/2026) carried across Runs #10 and #11. Confirmed via *Atlas Publico* and cross-referenced in the text of the later RE numero 2.801/2026.

Why this matters: This corrects the record. Manufacturers must ensure IFU repository uploads occur within 30 days per this specific resolution to remain compliant, and any internal tracking documents referencing the earlier incorrect resolution numbers should be updated.

MONITOR ANVISA Resolucao-RE numero 2.801/2026 - 141 device registration changes approved

2026-07-16

ANVISA approved 141 device registration/notification changes across 84 companies via Resolucao-RE numero 2.801, explicitly citing the RE 2.435/2026 IFU obligation. Full text via *AnvisaLegis*; coverage via *O Tempo*.

Why this matters: This batch approval demonstrates ANVISA actively enforcing the IFU-upload linkage as a condition for processing registration changes, reinforcing that RE 2.435 compliance is now operationally consequential.

Latin America / GCC

GENERAL

STRATEGIC SFDA MDS-G-029 - Risk Communication Guidance

Published 2026-07-09

Saudi FDA published guidance document MDS-G-029, establishing formal requirements for manufacturer and Authorized Representative risk communication to users and the public.

Why this matters: This formalizes risk-communication expectations that manufacturers previously handled on an ad hoc basis, aligning Saudi practice more closely with EU/US vigilance-communication norms.

MONITOR INVIMA safety alerts - GE angiography system and pediatric arterial cannula

Informe No. 100-2026 (2026-07-17); Alerta No. 199-2026 (within window)

INVIMA published Informe de Seguridad No. 100-2026 regarding a GE angiography system, and Alerta No. 199-2026 covering a pediatric arterial cannula (DLP) and Bio-Medicus adult cannula kit cardioplegia adapters.

Why this matters: Both alerts concern cardiovascular-adjacent devices used in high-acuity settings; institutions using these specific device models should review INVIMA's corrective guidance.

EAEU

GENERAL

STRATEGIC EAEU registration harmonization - 2026 framed as turning point ahead of Dec 31, 2027 deadline

Contextual/ongoing; final transition deadline 2027-12-31

Industry analysis frames 2026 as a turning point in EAEU device registration harmonization, with 18 months remaining until the final transition deadline of December 31, 2027 per *EAEU regulatory calendar analysis*. Given 180-220 business-day evaluation timelines, Class 3 (high-risk) devices should have begun the registration process by July 2026 to meet the deadline. Separately, Russian Government Resolution No. 2214 (effective January 8, 2026) extended certain national registration deadlines to December 31, 2027/2028.

Why this matters: Manufacturers of high-risk devices who have not yet initiated EAEU harmonized registration by this window risk missing the final 2027 transition deadline given the long evaluation timelines involved.

International / Standards / MDSAP / Cybersecurity

GENERAL

STRATEGIC ISO/TS 24971-2:2026 - AI/ML risk management guidance under ISO 14971

Published 2026-06-17

ISO published *ISO/TS 24971-2:2026*, providing risk-management guidance specific to machine-learning-enabled devices under the ISO 14971 framework. The technical specification explicitly excludes large language models and generative AI.

> Why this matters: This is a durable, directly applicable risk-management reference for AI/ML SaMD manufacturers, filling a gap that ISO 14971 alone did not address for ML-specific risk factors.

STRATEGIC ANSI/AAMI ST8:2026 - Hospital Steam Sterilizers, 7th Edition

Published 2026-07-14

AAMI published the 7th edition of ANSI/AAMI ST8:2026, the standard for hospital steam sterilizers per *AAMI announcement*.

> Why this matters: Sterilizer manufacturers and reprocessing departments must review the updated standard for design/validation changes affecting steam sterilization equipment compliance claims.

STRATEGIC ISO/WD TS 23485 - QMS guideline development progresses

Comments resolved 2026-07-07; DTS expected Sep 2026; publication targeted Jan 2027

Remaining comments on the draft ISO/WD TS 23485 quality-management-system guideline (a companion to ISO 13485) were resolved at a July 7, 2026 virtual meeting per *CoRE-SDO meeting summary*; DTS expected September 2026, publication targeted January 2027.

> Why this matters: This forthcoming guideline will provide practical implementation guidance for ISO 13485 QMS requirements, useful for manufacturers refining their quality systems ahead of the January 2027 target publication.

STRATEGIC MDSAP MDO Pilot Program extended to April 2027

Transmittal AO 2026-02 dated 2026-07-20; effective 2026-08-01

The Medical Device Organizations (MDO) pilot program was extended to April 2027 via *Transmittal AO 2026-02*, effective August 1, 2026. Participation limits raised to 40 facilities or 8% of an Auditing Organization's MDSAP facilities per the *MDSAP official announcement*.

> Why this matters: Extending and expanding the MDO pilot signals MDSAP's continued institutional confidence in the multi-facility organizational participation model, benefiting large multi-site device manufacturers.

MONITOR CISA ICS Medical Advisories (ICSMA) - continued weekly cadence

Throughout window; notable advisory 2026-07-02

CISA maintained its weekly ICS advisory cadence throughout the window, including a July 2, 2026 advisory covering WHILL Model C2/Model F power wheelchair software updates. Japanese JVN/JPCERT summaries confirm continuous ICSMA publication through July 23, 2026. Landing page: CISA ICS Advisories.

> Why this matters: Continued regular ICSMA cadence indicates sustained medical-device cybersecurity vulnerability disclosure activity; manufacturers of networked mobility and connected devices should monitor for advisories affecting their platforms.

Other Jurisdictions - Monitor

Jurisdiction	Status this period
New Zealand / Medsafe	No device-specific primary-source publication dated June 27-July 26, 2026 was isolated despite dedicated searches; device-notification cadence appears quiet this window.
Israel / AMAR	No AMAR-specific device primary-source action surfaced in-window; general Israeli MoH device pages carried no dated in-window updates.
United Arab Emirates / MOHAP	Only the standing registered medical product directory was found; no dated in-window regulatory action.
WHO Prequalification (IVDs)	No new in-window primary listing or policy update found.
IEC TC 62 / BSI / TUV SUD	No distinct dated in-window primary publication beyond the standing IEC 60601-1:2026 SER listing and Team-NB list update captured under EU.
WTO TBT (device-specific notifications)	A Korea notification referencing extracorporeal blood/fluid circuits for haemodialysers was seen in the general TBT tracker but full text and date could not be independently isolated; flagged for next-run direct check.

Key Upcoming Deadlines

Date / Days Out	Jurisdiction	What changes / Who is impacted / Action required
2026-07-31 5 days out	United Kingdom (MHRA)	WHAT CHANGES MHRA Annual Fee due (£300 per GMDN Level 2 category under the fee structure effective April 1, 2026). WHO IS IMPACTED All UK medical-device registrants. ACTION Complete fee payment via MHRA registration portal by July 31, 2026 to remain compliant. Source: assets.publishing.service.gov.uk
2026-08-01 6 days out	United States (FDA/CDRH)	WHAT CHANGES Revised eSTAR templates begin requiring an HF Submission Category declaration per the FDA Human Factors final guidance (nonbinding guidance finalized May 29, 2026). WHO IS IMPACTED Sponsors of 510(k), PMA, and De Novo submissions with any human factors content. ACTION Prepare pending 510(k)/PMA/De Novo submissions to declare the HF Submission Category in eSTAR; align HF content with the finalized guidance. Source: fda.gov
2026-08-01 6 days out	International (MDSAP)	WHAT CHANGES MDSAP MDO Pilot Program extension effective; participation limits raised to 40 facilities or 8% of an AO's MDSAP facilities. WHO IS IMPACTED Auditing Organizations and multi-facility manufacturers considering MDO pilot participation. ACTION Review revised participation terms if seeking MDO pilot enrollment; update quality-system documentation as applicable. Source: mdsap.global

Date / Days Out	Jurisdiction	What changes / Who is impacted / Action required
2026-08-05 10 days out	United States (FDA/CDRH)	WHAT CHANGES FDA MDUFA reauthorization public meeting. WHO IS IMPACTED Industry, patient organizations, and other MDUFA stakeholders. ACTION Register and participate; prepare public comments ahead of the August 7 deadline. Source: hklaw.com
2026-08-07 12 days out	United States (FDA/CDRH)	WHAT CHANGES FDA MDUFA reauthorization draft commitments letter - comment deadline. WHO IS IMPACTED All device manufacturers and industry associations. ACTION Submit comments on review-timeline performance goals and fee structures via the Federal Register docket. Source: hklaw.com
2026-08-28 33 days out	Taiwan (TFDA/MOHW)	WHAT CHANGES MOHW device fee revision consultation period closes. WHO IS IMPACTED Manufacturers marketing devices in Taiwan. ACTION Submit consultation comments on fee revisions if impacted. Source: emergobyul.com
2026-09-15 51 days out	United States (FDA/CDRH)	WHAT CHANGES FDA ASCA information-collection comment deadline. WHO IS IMPACTED Manufacturers using ASCA-accredited testing labs. ACTION Submit comments on ASCA information-collection renewal. Source: federalregister.gov
2026-09-23 59 days out	United Kingdom (MHRA)	WHAT CHANGES Sentencing in MHRA P900 enteral feeding pump fraud case. WHO IS IMPACTED Industry (as enforcement signal). ACTION Monitor sentencing outcome for enforcement-pattern read. Source: gov.uk
2026-09-30 66 days out	Malaysia (MDA)	WHAT CHANGES Malaysia-China Joint Evaluation Pilot Programme Phase 2 ends. WHO IS IMPACTED Manufacturers using the joint-evaluation pathway. ACTION Complete any Phase 2 submissions ahead of program transition. Source: mda.gov.my
2026-10 68 days out	European Union (MDCG)	WHAT CHANGES MDCG 2026-4 SSCP/SSP Production environment deployment (following July Playground). WHO IS IMPACTED Manufacturers with SS(C)P upload obligations. ACTION Validate SSCP/SSP data structures in Playground now to be Production-ready. Source: health.ec.europa.eu
2026-11-28 125 days out	European Union	WHAT CHANGES EUDAMED legacy-device UDI/Device data submission deadline. WHO IS IMPACTED All manufacturers with pre-mandatory-use legacy devices on the EU market. ACTION Complete legacy-device UDI/Device data migration into EUDAMED. Source: medtecheurope.org

Date / Days Out	Jurisdiction	What changes / Who is impacted / Action required
2026-12-02 129 days out	European Union	WHAT CHANGES AI Act Digital Omnibus - watermarking obligations begin. WHO IS IMPACTED Providers of AI systems generating synthetic content (including certain medical-imaging AI outputs). ACTION Ensure AI-output watermarking mechanisms are in place before this date. Source: lawandtechnology.eu
2026-12-31 158 days out	Switzerland (Swissmedic)	WHAT CHANGES Swissdamed transition period ends for devices already on market at July 1, 2026. WHO IS IMPACTED All manufacturers with devices on the Swiss market predating the July 1 mandatory-registration date. ACTION Complete Swissdamed registration for all pre-existing devices by year-end. Source: swissmedic.ch
2027-02-27 216 days out	European Union	WHAT CHANGES MDCG 2026-4 SS(C)P upload deadline - manufacturers must complete uploads. WHO IS IMPACTED MDR/IVDR manufacturers with SS(C)P obligations (Class III, implantables, IVDR high-risk). ACTION Complete SS(C)P uploads via EUDAMED SSCP/SSP module. Source: health.ec.europa.eu
2027-04-15 263 days out	Germany (BfArM)	WHAT CHANGES First formal DiGA AbEM data collection report due. WHO IS IMPACTED DiGA manufacturers. ACTION Establish AbEM data-collection infrastructure now for Q3/Q4 2026 collection period. Source: bfarm.de
2027-05-14 292 days out	Mexico (COFEPRIS)	WHAT CHANGES NOM-137-SSA1-2025 device labeling standard becomes mandatory. WHO IS IMPACTED All manufacturers selling into Mexico. ACTION Update device labeling to conform to NOM-137-SSA1-2025. Source: platiica.economia.gob.mx
2027-05-27 305 days out	European Union	WHAT CHANGES EUDAMED NB & Certificates module transition period ends. WHO IS IMPACTED Notified Bodies and manufacturers with legacy NB certificates. ACTION Complete NB certificate-registration migration. Source: medtecheurope.org
2027-12-31 523 days out	EAEU	WHAT CHANGES EAEU device registration harmonization final transition deadline. WHO IS IMPACTED All manufacturers with EAEU market presence, especially Class 3 (high-risk). ACTION Initiate harmonized-registration applications now given 180-220 business-day evaluation timelines. Source: kugno.ru

Macro-Trend Watch

Persistent cross-jurisdictional themes. Same themes carry across editions with new evidence appended.

UDI convergence and registration-database enforcement

AUSTRALIA | SWITZERLAND | EUROPEAN UNION

Australia TGA UDI mandatory for Class III and Class IIb devices effective July 1 per TGA UDI news; Switzerland Swissdamed mandatory registration effective July 1 per *Swissmedic guidance* with no grace period for vigilance devices; EU EUDAMED four modules mandatory since May 28, 2026 per *MedTech Europe* with legacy UDI data due November 28, 2026.

6-12 month outlook: Manufacturers face compounding administrative burden precisely because these deadlines cluster in July 2026 across unrelated regulatory systems. Consolidated global regulatory-data infrastructure (product master data, UDI generation, submission-tracking workflows) is now a strategic requirement, not a nice-to-have.

AI/ML SaMD governance consolidates into existing device frameworks

EUROPEAN UNION | SOUTH KOREA | TAIWAN | INTERNATIONAL (ISO)

EU AI Act Digital Omnibus *Regulation (EU) 2026/1744* integrates AI Act into MDR/IVDR conformity assessment; South Korea MFDS *Notice 2026-322* expands clinical-data waivers to all digital-device classes; Taiwan TFDA publishes *IMDRF-aligned GMLP guidance*; ISO publishes *ISO/TS 24971-2:2026* AI/ML risk-management guidance under ISO 14971 umbrella.

6-12 month outlook: Rather than build standalone AI-device laws, regulators are folding AI/ML obligations into established device frameworks. Manufacturers should expect AI-specific requirements to arrive as amendments to systems they already implement, not as new certification tracks - reducing duplicative infrastructure cost.

Notified Body capacity constraint managed via process efficiency, not headcount

EUROPEAN UNION

EU Implementing Regulation (EU) 2026/977 caps NB conformity-assessment timelines (30 days application review, 120 days QMS audit) per *Nelson Advisors*; MedTech Europe advocates *combined MDSAP/MDR/IVDR audits*; reported NB staff reductions circulate in industry press.

6-12 month outlook: The EU response to constrained NB capacity is process re-engineering (caps, combined audits) rather than assumed capacity expansion. Manufacturers should not count on faster NB turnaround from added headcount; instead, prepare cleaner submissions and consider MDSAP participation to leverage combined-audit pathways.

US convenience-kit cluster enforcement (United States)

UNITED STATES

Nine linked recall classifications posted July 23 (Z-2779-2026 through Z-2787-2026) covering convenience kits (including Foley catheter trays) per the FDA recalls database; FDA's July 9 Early Alert attributes the underlying defect to recalled BD ChloraPrep 1 mL / FREPP 1.5 mL applicator components included in the kits.

6-12 month outlook: Either a widening BD applicator recall root-cause investigation or a structurally fragile convenience-kit supply chain. Kit assemblers incorporating the recalled BD ChloraPrep/FREPP applicator components should conduct supplier audits immediately and expect additional linked classifications in H2 2026.

Asia-Pacific submission digitization and cross-border reliance

CHINA | TAIWAN | MALAYSIA | THAILAND

China's mandatory *Solicita certificate system* effective July 3; Taiwan's new *e-submission system for Class I devices*; Malaysia-Thailand *full implementation* of regulatory reliance; Malaysia-China Joint Evaluation Pilot Phase 2 launched July 1.

> 6-12 month outlook: Regional wave of administrative modernization independent of any single coordinating body. Manufacturers pursuing multiple APAC markets can increasingly leverage single submissions across reliance pathways, reducing duplicate documentation cost.

Global vigilance synchronization - same device model surfacing across multiple regulators within days

CANADA | UNITED KINGDOM | UNITED STATES | IRELAND

Philips Allura Xper FD10 appeared in both Health Canada's recall list and MHRA's Field Safety Notice batch within the same week; Impella-related field actions appeared at both FDA and *HPRA* in the same window.

> 6-12 month outlook: Manufacturers are increasingly notifying multiple regulators in near-parallel rather than staggering disclosures. Vigilance-communication playbooks should assume simultaneous multi-market disclosure as the operating norm, and vigilance databases should be interrogated cross-jurisdictionally rather than one regulator at a time.

Multi-run 'must verify' items resolved this month

EUROPEAN UNION | SOUTH KOREA | BRAZIL

AI Act Digital Omnibus OJEU publication confirmed as *Regulation (EU) 2026/1744* on July 24; MFDS Korea standards package notice number resolved as *Notice No. 2025-45*; ANVISA IFU-upload resolution number resolved as *RE nº 2.435/2026* (correcting prior guesses of RE 2438 and RE 2260).

> 6-12 month outlook: Three long-standing tracking ambiguities closed in one window - a materially cleaner running-carryover ledger. India CDSCO drafts (G.S.R. 515(E) and 269(E)/270(E)) remain the most persistent unresolved item, now spanning three consecutive runs.

Methodology

This monthly deep-dive covers the June 27 through July 26, 2026 window across the full RegTalk monthly source scope: FDA/CDRH (guidances, warning letters, recalls, Early Alerts, Federal Register, MDUFA), Health Canada, COFEPRIS, MDCG and European Commission (EUR-Lex, MDCG guidance library, Team-NB, MedTech Europe, HPRA), MHRA (GOV.UK), Swissmedic (Swissdamed), BfArM (DiGA), NMPA/CMDE, PMDA, MHLW, MFDS, TFDA, TGA, MDA Malaysia, Thai FDA, CDSCO (Gazette Notifications), INVIMA, ANVISA (AnvisaLegis), SFDA, EAEU regulatory calendars, ISO/AAMI standards, MDSAP, CISA ICSMA. Extended 7 days beyond Run #11 (through July 26, 2026) and reached back to June 27, 2026 to close pre-Run-10 backfill. All items carry primary-source URLs where available; secondary sources are labelled and used only where primary access was blocked (EUR-Lex robots-block for the AI Act Digital Omnibus, corroborated via Council PE-CONS 30/26 and multiple law-firm analyses). Company items are confined to company_specific / watchlist / spotlight / macro_themes per the standing content rule. 59 total items were reviewed; 17 tier CRITICAL/STRATEGIC lift into the executive summary; the remainder route to jurisdictional sections and the watchlist. Verification status: three multi-run 'must verify'

items closed in-window (EU AI Act Digital Omnibus OJEU publication, MFDS Korea Notice 2025-45, ANVISA RE 2.435/2026); India CDSCO drafts remain unresolved across three consecutive runs and are flagged for continuity. Factcheck notes: EUR-Lex direct fetches returned robots-block errors, exact MDCG 2026-4 Playground go-live day within July not isolated, WTO TBT device-specific coverage light this run, no in-window primary-source device action found for New Zealand Medsafe, Israel AMAR, or UAE MOHAP.

Sourcing: Primary regulator and official-source links are included inline. Secondary analyses and industry commentary are attributed by name. Full sourcing available on request - contact Arazy Group MedTech Regulatory Technology.

Sources cited inline. Prepared by Arazy Group MedTech Regulatory Technology. Information provided for awareness; not legal or regulatory advice. Confirm current status on each agency's official website before acting.