

# REG Talks

## Global Regulatory Information Digest

Weekly

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# This Week's Synthesis

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

- EUDAMED operational countdown reaches its climax – the May 26–28 stretch compresses three EU/UK deadlines (MDR Class III custom-made / IVDR Class C NB applications, NI legacy registration sunset, EUDAMED four-module mandatory-use) into 72 hours.
- Cardiac-device theme continues into a third consecutive week: Abiomed Impella Controller Early Alert (1 death, software fix) and Bolton Medical RelayPro Class I recall (3 deaths, hardware failure) follow GE ApexPro and Boston Scientific ACCOLADE in prior weeks. PMS plans for telemetry, EP, circulatory-support, and stent-graft product lines warrant a refresh.
- NAMIC convenience-kit cluster effectively closed at 4 downstream packagers; no 5th identified in this monitoring window. Supplier-component vigilance pattern now formalized at IMDRF level via the open supplier-control consultation.
- July 1, 2026 emerges as the next major multi-jurisdiction compliance cliff: SWISSDAMED Product Module mandatory, TGA AusUDID for Class III/IIb implantables, Oman Class C/D requirements. Sponsors with presence in two or more should sequence work backwards from July 1 now.
- UK regulatory framework reform window opens narrowly: MHRA Stakeholder Impact Survey on the draft 2026 Regulations closes June 19. This is the primary influence window for pre-market UKCA routes, international reliance, and SaMD/PCCP – response preparation should be allocated this week.

## REGULATORY INTELLIGENCE SPOTLIGHT

### EUDAMED four-module trigger - 4 days out

Final operational week before the May 28, 2026 mandatory-use date for Actor Registration, UDI/Devices, Notified Bodies & Certificates, and Market Surveillance modules ([European Commission update](#)). Manufacturers and Authorized Representatives without an SRN must complete Actor Registration this week. From May 28 onward, paper or national-portal-based filings for the four modules become out-of-spec; new UDI-DIs have zero grace period (legacy UDI-DI grace runs to November 27, 2026).

### Implementing Regulation 2026/977 in force May 25

Commission Implementing Regulation (EU) 2026/977, published in the OJEU on May 5, 2026, entered into force May 25 – within this monitoring window ([European Commission – New Regulations](#)). Uniform NB conformity-assessment timeframes: 30/120/90/20-day caps (application+contract / QMS audit / product verification / decision); recertification capped at 90/20-day. Operative for NB-manufacturer written agreements signed after February 25, 2027.

### Two cardiac-device Class I actions in one week - one Early Alert, one recall, 4 deaths combined

FDA issued an Early Alert on May 21 for all Abiomed Automated Impella Controllers after a software bug causing ~35-second pump stoppage was tied to 2 serious injuries and 1 death ([FDA Early Alert](#)). On May 20, FDA classified the Bolton Medical RelayPro Thoracic Stent Graft as Class I after 3 deaths linked to proximal clasp disconnection preventing graft release ([FDA Class I recall](#)). Two consecutive weeks of cardiac-adjacent enforcement signal.

## Regulatory Intelligence Detail

Coverage window: May 18 – May 24, 2026. Mode: Weekly. 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** EUDAMED four-module mandatory-use trigger – 4 days out

Effective May 28, 2026

Actor Registration, UDI/Devices, Notified Bodies & Certificates, and Market Surveillance modules switch to mandatory-use. Triggered by Commission Decision (EU) 2025/2371 (OJEU November 27, 2025). From May 28, paper or national-portal-based filings for these four modules are out-of-spec ([European Commission update](#)).

**Why this matters:** This is the highest-intensity compliance window of 2026 YTD. Sponsors without an SRN must complete Actor Registration this week. New UDI-DIs have zero grace period from May 28; legacy UDI-DI grace runs to November 27, 2026. The May 26–28 stretch also compresses MDR Class III custom-made / IVDR Class C NB-application cutoffs and the Northern Ireland legacy registration sunset into 72 hours.

**STRATEGIC** Implementing Regulation 2026/977 enters into force

In force May 25, 2026; operative for new NB agreements after February 25, 2027

Uniform NB conformity-assessment timeframes are now binding upper bounds: 30 days (application + contract signature), 120 days (initial QMS audit), 90 days (product verification), 20 days (decision + certificate issuance). Recertification capped at 90/20-day. Operative for NB-manufacturer written agreements signed after February 25, 2027 ([European Commission – New Regulations](#)).

**Why this matters:** Sponsors can now plan NB engagement around predictable upper bounds for the first time since MDR application. The 120-day QMS audit cap is the longest single sub-clock and the most likely to bind capacity-constrained NBs. Internal NB SLAs, escalation triggers, and recertification timelines need updating before the February 25, 2027 operative date.

**STRATEGIC** Team-NB 2025 Annual Sector Survey – capacity still available pre-deadline

Published May 19, 2026

Team-NB confirms that European Notified Bodies currently have availability for new conformity-assessment applications. The survey notes this may shift as outstanding applications accumulate closer to the MDR/IVDR end-of-transition cliff ([Team-NB 2025 Sector Survey](#)).

**Why this matters:** Sponsors weighing late filings should treat this as a closing window. Industry commentary notes the favorable capacity picture is unlikely to hold into Q4 2026 as backlogs build. Pre-application QMS readiness becomes a more valuable input than ever, since rework loops inside an assessment now carry hard timeline consequences under 2026/977 caps.

## United Kingdom - MHRA

### GENERAL

**CRITICAL** MHRA Stakeholder Impact Survey – draft Medical Devices (Amendment) Regulations 2026

Open through June 19, 2026 (launched May 11)

MHRA's Stakeholder Impact Survey on the draft Medical Devices (Amendment) Regulations 2026 is running through 23:59 UK time on June 19, 2026. Survey covers pre-market UKCA conformity-assessment routes, international reliance pathways (US/Canada/Australia), SaMD and PCCP pathway, IVD reclassification (A-D), and downstream alignment with the future regulatory framework. Distinct from the in-force June 2025 PMS regime, which already carries the revised vigilance reporting timelines ([MHRA call for evidence](#)).

**Why this matters:** This is the primary influence window for GB framework reform. EU CE-marking as a permanent reliance route is being handled separately and is not in this survey. Regulatory affairs teams should prepare quantitative responses on pre-market routes and international-reliance proposals. Once approved, the SI is expected to come into force ~6 months after laying, with implementation not before early 2027 (up to 3-year transitional period for devices, 5 years for IVDs).

**STRATEGIC** MHRA clinical investigations guidance – fee-waiver expansion now includes Class III

Updated May 19, 2026

The 'Clinical Investigations for Medical Devices' guidance page was updated May 19. The fee-waiver programme for micro and small UK enterprises has been extended for 2026–2027 (April 20, 2026 to April 5, 2027) and now includes Class III devices for the first time ([MHRA guidance](#)).

**Why this matters:** For small UK device companies running first-in-human or pivotal studies on Class III products, the fee waiver materially lowers UK study start-up costs. Combined with the new Clinical Trials Framework's 30-day combined application and 14-day silence rule, UK is becoming meaningfully attractive as a pilot jurisdiction for higher-risk device sponsors.

**STRATEGIC** MHRA-NICE Real-World Evidence Scientific Dialogue – relaunched with devices in scope

Relaunched May 20, 2026

The MHRA-NICE RWE Scientific Dialogue programme transitioned from pilot to established service. Critically, the updated scope now explicitly accepts applications relating to RWE and medical devices, with Approved Body involvement where applicable ([MHRA-NICE RWE SD page](#)). Expression-of-interest window open through August 17, 2026.

**Why this matters:** Device sponsors gain a structured pre-approval pathway for getting joint regulator + HTA feedback on RWE study design – a notable gap until now. Programmes building post-market evidence under PCCP-style change controls or AI/ML lifecycle plans should prioritize an application this cycle.

**STRATEGIC** Device Safety Information DSI/2026/003 – blood transfusion giving set

Issued May 20, 2026

MHRA published DSI/2026/003 on the risk of severe harm – including haemolysis and brain damage – when an IV infusion giving set is used instead of a blood transfusion giving set. References a specific MNSI–investigated case ([MHRA DSI/2026/003](#)).

**Why this matters:** Treated as STRATEGIC because the DSI carries process–level guidance (correct set identification, point–of–care checks) that affects all NHS trusts and manufacturers of IV infusion / transfusion sets. Manufacturers of overlapping set families should re–verify labeling differentiation and instructions for use.

## Switzerland

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**GENERAL****CRITICAL** SWISSDAMED Product Module – 6 weeks to mandatory use

Effective July 1, 2026

From July 1, all new medical devices, IVDs, and procedure packs must be registered in the SWISSDAMED Product Module before first placing on the Swiss market. Vigilance–event immediate–trigger rule eliminates the grace period for any device with an incident post–July 1 (*Swissmedic SWISSDAMED*). Swissmedic's PMS focus campaign is active in parallel.

**Why this matters:** Most underappreciated compliance risk: a single post–July 1 vigilance event on a non–registered device triggers retrospective registration obligations on a hard clock. CH–REPs and importers should validate registration status for every SKU placed on the Swiss market in the next six weeks, not just new launches.

## United States - FDA / CDRH

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**GENERAL****STRATEGIC** FDA TEMPO digital–health pilot FAQ updated

Updated May 18, 2026

CDRH refreshed the TEMPO (Technology–Enabled Meaningful Patient Outcomes for Digital Health Devices) pilot FAQ page. FDA began sending follow–up information requests to candidate pilot participants in March 2026 and intends to select up to approximately ten US–based manufacturers per clinical–use area ([FDA TEMPO FAQ](#)).

**Why this matters:** SaMD and digital–health pipeline holders should re–evaluate whether to seek inclusion in the active selection process. TEMPO participation may shape the documentation and post–market reporting expectations that FDA generalizes into future SaMD lifecycle guidance.

**COMPANY–SPECIFIC**

### STRATEGIC Abiomed Automated Impella Controller – Early Alert (software restart, 1 death)

Classified May 21, 2026

FDA issued an Early Alert for all Automated Impella Controllers after a software bug can cause the AIC to restart – screen goes black, pump stops for ~35 seconds – under specific left ventricular pressure conditions. Two serious injuries and one death reported as of April 27, 2026. Abiomed is developing a software patch; devices remain in service with updated instructions ([FDA Early Alert](#)).

**Why this matters:** Tracks as STRATEGIC on confirmed mortality signal and continued software-update-as-CAPA pattern across cardiac devices. This is the same Class-I-remediation-via-firmware pathway observed earlier in 2026 across Boston Scientific ACCOLADE, Tandem Mobi, Trividia TRUE METRIX, and GE ApexPro – regulators are accepting software corrections in lieu of physical recall where technically feasible.

### STRATEGIC Bolton Medical RelayPro Thoracic Stent Graft – Class I (3 deaths)

Classified May 20, 2026

FDA Class I recall for the Bolton Medical RelayPro Thoracic Stent-Graft System (32mm and above, non-bare stent configuration). In some cases the graft cannot unclasp from the delivery system because the proximal clasp is disconnected from the outer control tube, potentially requiring open surgical conversion. Three deaths reported as of April 23 ([FDA Class I recall](#)).

**Why this matters:** Worldwide distribution. Combined with the Abiomed AIC Early Alert, this gives two cardiac-adjacent Class I actions with confirmed mortality in the same week. Sponsors of vascular access and circulatory-support devices should refresh PMS clustering for catheter-deployment failure modes.

### STRATEGIC Medline NAMIC convenience-kit cluster – closed at 4 downstream packagers

Status confirmed for week ending May 24, 2026

Cluster is closed at 4 Class I downstream packagers: American Contract Systems (May 7), Medical Action Industries (May 7), AVID Medical (May 12), Aligned Medical Solutions / Windstone (May 11) ([Aligned Medical Solutions recall](#)). No 5th packager identified in the May 18–24 window. Originating issuance: FDA Warning Letter to Medline (CMS #723866, March 25, 2026).

**Why this matters:** Cluster effectively closed but continue monitoring through June for late-identified distributors. Sponsors using third-party syringes in convenience kits should treat this cycle as a template for supplier-component vigilance triggers and downstream packager mapping.

## United States - CMS

### GENERAL

#### STRATEGIC CMS/FDA RAPID coverage pathway – comment period on NTAP alternative repeal closes June 9

Comment period closes June 9, 2026 (CMS-1849-P)

The CMS–FDA Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway was announced April 23, 2026. Under RAPID, CMS issues a proposed National Coverage Determination the same day FDA grants market authorization for eligible Breakthrough Devices. The NTAP alternative pathway repeal proposal is open for comment through June 9, 2026 ([CMS.gov](#)).

**Why this matters:** For Breakthrough Device sponsors, RAPID materially compresses the path from market authorization to coverage. Companies relying on the NTAP alternative pathway should comment by June 9 if they expect transition impact. RAPID's same-day proposed-NCD mechanic also changes the calculus for prioritizing Breakthrough Designation in pipeline planning.

## Australia - TGA

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### GENERAL

**CRITICAL** TGA UDI compliance–timeframes guidance updated; Class III/IIb implantables deadline July 1

Updated May 22, 2026; deadline July 1, 2026 (40 days out)

TGA published a substantive update to its UDI compliance–timeframes guidance on May 22. Updates include clarified definition of 'existing devices', alignment of EU MDD–to–MDR and IVDD–to–IVDR transition language, and a new compliance–date summary table ([TGA UDI guidance](#)).

**Why this matters:** Class III medical devices and Class IIb implantables placed on the Australian market must comply with AusUDID UDI requirements from July 1, 2026. Sponsors should validate UDI assignment, GS1/HIBCC issuance, and AusUDID submission status now – the updated guidance closes ambiguity on 'existing device' scoping that was previously used to defer compliance.

## Malaysia - MDA

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### GENERAL

**CRITICAL** Designated Medical Device (Aesthetic) Order 2026 – effective June 1

Effective June 1, 2026 (8–day countdown)

MDA Malaysia has officially gazetted the Medical Device (Designated Medical Device) Order 2026 designating aesthetic medical devices as a regulated category under Act 737. Aesthetic device manufacturers and importers must be registered with MDA from June 1 (*MDA Malaysia*).

**Why this matters:** Sponsors of dermal lasers, energy–based aesthetic systems (RF, ultrasound, cryolipolysis), and related devices have 8 days to complete MDA registration. Confirm whether the product portfolio includes listed devices; if so, begin or finalize the MDA registration process this week.

## Thailand - Thai FDA

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### GENERAL

**CRITICAL** Medical device labeling and IFU regulation – effective June 20

Effective June 20, 2026 (27–day countdown)

Thailand's Ministry of Public Health finalized new medical device labeling and Instructions for Use (IFU) requirements in December 2025, effective June 20, 2026. Bilingual Thai–English labeling is now acceptable; previously Thai–only was strictly required (*Thai FDA news*).

**Why this matters:** Manufacturers, importers, and license holders should verify label and IFU content against the updated requirements and prepare label–change supplements where needed. The bilingual allowance reduces localization cost but specific format mandates still apply.

## Korea - MFDS

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## GENERAL

### **STRATEGIC** Medical Devices Act amendment passes National Assembly

Passed May 8, 2026

Partial amendments to the Medical Devices Act provide a government-level direct-supply system for medical devices with no domestic alternative or urgent public health need, and prohibit advertising of unapproved AI medical devices. Confirmed via Seoul Economic Daily citing the MFDS statement (*\*Seoul Economic Daily\**).

**Why this matters:** AI/ML device sponsors targeting the Korean market should re-verify advertising content (clinic-facing and direct-to-consumer) against the new advertising ban. The government-supply provision creates a backup pathway for orphan device categories where domestic supply has historically been thin.

### **STRATEGIC** MFDS Notice 2026-34 - RWE for post-approval device indication changes

Effective April 28, 2026

MFDS Notice 2026-34 formally permits Real-World Evidence (RWE) as clinical evidence for modifying approved indications or instructions for use, provided the change remains within the originally cleared intended use envelope ([MFDS notice listing](#)).

**Why this matters:** Sponsors with already-approved devices in Korea can now leverage post-market data for label expansions and IFU updates without re-running prospective clinical trials. Aligns Korea with FDA and MHRA on accepting RWE as a primary evidence source for post-approval changes - a notable convergence point.

## Colombia - INVIMA

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### GENERAL

#### **STRATEGIC** UDI-DI Phase 3 enforcement now active for Class IIa / Category I IVDs

Enforcement active since February 8, 2026

Phase 3 of INVIMA's UDI regime under Resolution 1405 of 2022 closed February 8, 2026. Class IIa medical devices and Category I IVDs registered before February 7, 2024 were required to have UDI-DI codes reported and validated against INVIMA's semantic standard. Non-compliant products are now in active enforcement ([INVIMA](#)).

**Why this matters:** Latin America's UDI infrastructure is now operational across the highest-volume device classes for the Colombian market. Sponsors should validate semantic-standard mapping (GS1, HIBCC, or INVIMA-issued) against the active enforcement window. Failure to validate creates registration suspension risk on routine renewals.

## EAEU - Eurasian Economic Commission

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### GENERAL

#### **STRATEGIC** Single sterilization-site inspection replaces multiple checks

Adopted April 27, 2026

The EEC Council amended the Requirements for Implementation, Maintenance, and Evaluation of QMS for Medical Devices (Decision No. 106, November 10, 2017). Multiple independent sterilization-site inspections are replaced by a single coordinated assessment across EAEU member states ([EAEU](#)).

**Why this matters:** Sponsors with contract-sterilization arrangements supplying multiple EAEU member states should expect lower inspection-burden costs and faster site-qualification timelines. Update site-master files and supplier-control documentation to reflect the consolidated assessment workflow.

## IMDRF

### GENERAL

**STRATEGIC** Public consultation – supplier–control guidance (QMS WG)

Open May 14, 2026 through July 2026

IMDRF opened public consultation on the draft 'Guidance on the Control of Products and Services Obtained from Suppliers' developed by the IMDRF QMS Working Group ([IMDRF consultation](#)).

**Why this matters:** This guidance is positioned to harmonize supplier–control expectations across IMDRF jurisdictions and will likely flow into MDSAP audit criteria within 12–18 months. Sponsors with complex contract–manufacturing or distributed supplier networks should review the draft and submit comments – especially on traceability and downstream–packager scope, given the recent NAMIC convenience–kit cluster experience.

## MDSAP

### GENERAL

**STRATEGIC** Malaysia MDA joins MDSAP as affiliate member

Effective via portal announcement updated May 22, 2026

MDA Malaysia confirmed Malaysia is now officially a member of the Medical Device Single Audit Program (MDSAP) as an Affiliate Member. MDSAP reports are now accepted for pre–market submissions to MDA (*MDA portal*).

**Why this matters:** Sponsors holding active MDSAP certificates can now leverage them in Malaysian device submissions, reducing duplicate audit burden for the MDA pathway. Combined with the June 1 aesthetic–device order, this gives multi–market sponsors a meaningful efficiency lever for Southeast Asia expansion.

## Key Upcoming Deadlines

Date / Days Out	Jurisdiction	What changes / Who is impacted / Action required
2026–05–26 2 days out	EU (EU-27)	<p><b>WHAT CHANGES</b> MDR Class III custom–made and IVDR Class C Notified Body application milestone takes effect.</p> <p><b>WHO IS IMPACTED</b> Manufacturers of MDR Class III custom–made devices and IVDR Class C IVDs; their Notified Bodies and ARs.</p> <p><b>ACTION</b> Submit NB applications before the cutoff; coordinate with NBs on intake capacity.</p> <p>Source: <a href="#">primary source</a></p>

Date / Days Out	Jurisdiction	What changes / Who is impacted / Action required
2026-05-27 3 days out	UK / Northern Ireland (MHRA)	<p><b>WHAT CHANGES</b> Northern Ireland legacy device registration sunset. Devices previously relying on legacy registration must be on a current registration pathway.</p> <p><b>WHO IS IMPACTED</b> Manufacturers and UK Responsible Persons for devices placed on the NI market.</p> <p><b>ACTION</b> Confirm devices are registered through the current MHRA/EU pathway prior to sunset.</p> <p>Source: <a href="#">primary source</a></p>
2026-05-28 4 days out	EU (EU-27)	<p><b>WHAT CHANGES</b> EUDAMED four modules switch to mandatory-use: Actor Registration, UDI/Devices, Notified Bodies &amp; Certificates, Market Surveillance.</p> <p><b>WHO IS IMPACTED</b> All manufacturers, ARs, importers, Notified Bodies, and competent authorities operating under MDR/IVDR.</p> <p><b>ACTION</b> Complete Actor Registration and obtain SRN if not already in hand; ensure UDI/device records and NB certificate links are populated.</p> <p>Source: <a href="#">primary source</a></p>
2026-06-01 8 days out	Malaysia (MDA)	<p><b>WHAT CHANGES</b> Designated Medical Device (Aesthetic) Order 2026 takes effect, bringing aesthetic devices under MDA controls.</p> <p><b>WHO IS IMPACTED</b> Manufacturers and importers of aesthetic devices (e.g. dermal lasers, energy-based aesthetic systems).</p> <p><b>ACTION</b> Confirm whether product portfolio includes listed devices; begin MDA registration process if so.</p> <p>Source: <a href="#">primary source</a></p>
2026-06-09 16 days out	United States (CMS)	<p><b>WHAT CHANGES</b> Comment period closes on CMS-1849-P (NTAP alternative pathway repeal under RAPID).</p> <p><b>WHO IS IMPACTED</b> Breakthrough Device sponsors and current/prospective NTAP alternative pathway users.</p> <p><b>ACTION</b> Submit public comments via regulations.gov before close of comment.</p> <p>Source: <a href="#">primary source</a></p>
2026-06-19 26 days out	UK (MHRA)	<p><b>WHAT CHANGES</b> MHRA Stakeholder Impact Survey on the draft Medical Devices (Amendment) Regulations 2026 closes.</p> <p><b>WHO IS IMPACTED</b> All UK-market device sponsors, ARs, and Approved Bodies.</p> <p><b>ACTION</b> Submit quantitative responses on pre-market UKCA routes, international reliance, SaMD/PCCP, and IVD reclassification impacts.</p> <p>Source: <a href="#">primary source</a></p>
2026-06-20 27 days out	Thailand (Thai FDA)	<p><b>WHAT CHANGES</b> Updated medical device labeling and IFU regulations take effect, including bilingual Thai-English allowance.</p> <p><b>WHO IS IMPACTED</b> Manufacturers, importers, and license holders of registered medical devices in Thailand.</p> <p><b>ACTION</b> Verify label and IFU content against updated requirements; prepare label-change supplements as needed.</p> <p>Source: <a href="#">primary source</a></p>

Date / Days Out	Jurisdiction	What changes / Who is impacted / Action required
2026-07-01 38 days out	Switzerland / Australia / Oman	<p><b>WHAT CHANGES</b> SWISSDAMED Product Module mandatory-use; TGA AusUDID requirements for Class III and Class IIb implantable devices; Oman Class C/D requirements take effect.</p> <p><b>WHO IS IMPACTED</b> Manufacturers and ARs operating in Switzerland (all classes via SWISSDAMED), Australia (Class III/IIb implantables for UDI), Oman (Class C/D).</p> <p><b>ACTION</b> Register SKUs in SWISSDAMED; assign/submit UDIs in AusUDID; submit dossiers to MOH Oman for Class C/D.</p> <p>Source: <a href="#">primary source</a></p>
2026-08-02 70 days out	EU (EU-27)	<p><b>WHAT CHANGES</b> EU AI Act high-risk system requirements become applicable. Devices/IVDs incorporating AI/ML qualifying as high-risk per Annex III intersect with MDR/IVDR conformity assessment.</p> <p><b>WHO IS IMPACTED</b> Manufacturers of AI/ML-enabled medical devices, IVDs, and SaMD; their Notified Bodies.</p> <p><b>ACTION</b> Confirm AI/ML classification under AI Act; align conformity assessment, risk management, and PMS with both MDR/IVDR and AI Act.</p> <p>Source: <a href="#">primary source</a></p>
2026-11-01 161 days out	China (NMPA)	<p><b>WHAT CHANGES</b> Revised Good Manufacturing Practice for Medical Devices (Announcement 107/2025) becomes effective.</p> <p><b>WHO IS IMPACTED</b> Domestic and overseas manufacturers of devices and IVDs registered in China; site-audited operations.</p> <p><b>ACTION</b> Update QMS documentation, internal audit programs, and supplier-control procedures to the revised GMP; prepare for NMPA on-site inspection cycle.</p> <p>Source: <a href="#">primary source</a></p>
2026-11-27 187 days out	EU (EU-27)	<p><b>WHAT CHANGES</b> EUDAMED legacy device registration deadline – all legacy MDD/AIMDD/IVDD devices still on the EU market must have completed EUDAMED registration.</p> <p><b>WHO IS IMPACTED</b> Manufacturers and ARs holding legacy CE certificates for devices still placed on the EU market.</p> <p><b>ACTION</b> Complete EUDAMED device registration for all legacy SKUs; reconcile any orphaned legacy product codes.</p> <p>Source: <a href="#">primary source</a></p>
2026-12-31 221 days out	Switzerland (Swissmedic)	<p><b>WHAT CHANGES</b> SWISSDAMED transition completion – end of the migration window for Swiss device registrations.</p> <p><b>WHO IS IMPACTED</b> All manufacturers, CH-REPs, and importers placing devices on the Swiss market.</p> <p><b>ACTION</b> Confirm all Swiss device registrations have been migrated into SWISSDAMED before year end.</p> <p>Source: <a href="#">primary source</a></p>

Date / Days Out	Jurisdiction	What changes / Who is impacted / Action required
2027-03-01 281 days out	China (NMPA)	<p><b>WHAT CHANGES</b> NMPA's 22 recommended standards from the 2026 plan become applicable for CMDE review reference.</p> <p><b>WHO IS IMPACTED</b> Sponsors with active CMDE submissions and post-approval lifecycle work touching the 22 affected standards.</p> <p><b>ACTION</b> Map current dossiers against the 22 standards; plan dossier supplements where superseded standards are cited.</p> <p>Source: <a href="#">primary source</a></p>
2027-05-28 734 days out	EU (EU-27)	<p><b>WHAT CHANGES</b> Pre-2026 EU certificates upload deadline – all CE certificates issued before 2026 must be uploaded into EUDAMED.</p> <p><b>WHO IS IMPACTED</b> Notified Bodies and certificate holders for any pre-2026 EU CE certificate still in scope.</p> <p><b>ACTION</b> Coordinate with NBs to confirm full certificate set is uploaded; reconcile orphaned or unlinked certificates.</p> <p>Source: <a href="#">primary source</a></p>

## Macro-Trend Watch

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

### Global UDI Convergence

[EU](#) | [UNITED STATES](#) | [AUSTRALIA](#) | [SWITZERLAND](#) | [COLOMBIA](#) | [SAUDI ARABIA](#)

EUDAMED UDI module mandatory May 28 ([EC update](#)). TGA UDI guidance updated May 22 with July 1 Class III/IIb implantables deadline ([TGA UDI guidance](#)). SWISSDAMED Product Module mandatory July 1 (*Swissmedic*). INVIMA UDI Phase 3 enforcement now active for Class IIa / Category I IVDs ([INVIMA](#)). SFDA Saudi Arabia continues UDI submission ramp-up.

**6-12 month outlook:** Manufacturers should consolidate UDI assignment, GS1/HIBCC issuance, and label-on-device printing under a single global program. Multiple jurisdictions are now reading from the same GUDID/EUDAMED-style data structures. Expect more jurisdictions (LATAM, GCC) to add UDI requirements through 2026-2027.

### AI/ML and SaMD Lifecycle Oversight

[UNITED STATES](#) | [EU](#) | [UNITED KINGDOM](#) | [KOREA](#) | [CHINA](#)

FDA TEMPO pilot FAQ refreshed May 18 with active participant selection ([FDA TEMPO](#)). MFDS amendment passes National Assembly with explicit ban on advertising unapproved AI devices (\*Seoul Economic Daily\*). EU AI Act high-risk requirements apply August 2 and intersect with MDR/IVDR. UK MHRA-NICE RWE SD relaunched with devices in scope ([MHRA](#)). NMPA 2026 Standards Plan covers AI / robotic devices among six prioritized domains.

**6-12 month outlook:** Sponsors should expect convergent expectations on model documentation, change control (PCCP-style), and post-market performance monitoring across all four major regulators. AI/ML programs that satisfy FDA PCCP and EU AI Act QMS-overlay obligations will be closest to compliant across the board. Korea's advertising ban adds a marketing-content risk vector that did not exist before.

## EUDAMED Operationalization and EU Framework Tightening

### EU

EUDAMED four modules mandatory May 28 ([EC update](#)). Implementing Regulation 2026/977 in force May 25, with 30/120/90/20-day NB conformity-assessment caps ([EC](#)). Team-NB 2025 Sector Survey confirms NB capacity is currently available but expected to compress (\*Team-NB\*). Legacy device registration deadline holds at November 27, 2026.

**6-12 month outlook:** EU regulatory cost and time-to-market are becoming more predictable but also less flexible. Build EUDAMED submission discipline and NB engagement playbooks now; expect fewer accommodations for late filers as 2026-2027 progresses.

## Convergence of UK and EU Clinical Evidence Frameworks (Diverging Speeds)

### UNITED KINGDOM | EU

MHRA Clinical Investigations guidance updated May 19 with fee-waiver extension to Class III ([MHRA](#)). MHRA-NICE RWE Scientific Dialogue relaunched with devices explicitly in scope ([MHRA-NICE RWE SD](#)). MHRA Stakeholder Impact Survey on draft 2026 Regulations open through June 19 ([MHRA call for evidence](#)). EU MDR/IVDR clinical evaluation requirements continue under existing MDCG guidance with no equivalent acceleration.

**6-12 month outlook:** UK is becoming an increasingly attractive first-in-human jurisdiction for device sponsors, particularly for higher-risk and combination products. Re-evaluate study placement decisions over the 2026-2027 cycle. The MHRA-NICE RWE programme also creates a structured pre-approval feedback pathway that has no EU equivalent.

## Notified Body Capacity and Timeline Discipline (EU)

### EU

Implementing Regulation 2026/977 caps now binding upper bounds; operative for NB-manufacturer agreements signed after February 25, 2027 ([EC](#)). Team-NB 2025 Annual Sector Survey confirms current availability ([Team-NB](#)). Major NBs (BSI, TUV SUD, TUV Rheinland, DEKRA, DNV) are realigning capacity planning around predictable upper bounds.

**6-12 month outlook:** Sponsors should treat NB slot allocation as a finite resource on a predictable schedule. Pre-application QMS readiness becomes more valuable than ever; rework loops within an assessment now carry hard timeline consequences. The favorable capacity picture is unlikely to hold into Q4 2026.

## Software-Update-as-Class-I Remediation

### UNITED STATES | CANADA

Abiomed Automated Impella Controller Early Alert (May 21) – software patch in development for ~35-second pump restart bug, 1 death reported ([FDA](#)). Joins prior 2026 examples: Boston Scientific ACCOLADE (SMR6 firmware upgrade, May 7), Tandem Mobi insulin pump, Trividia TRUE METRIX BGM, GE ApexPro CARESCAPE. FDA and Health Canada continue accepting software corrections in lieu of physical recall where technically feasible.

**6-12 month outlook:** Manufacturers of connected/cybersecure devices should formally build software-update-as-CAPA into their corrective-action playbooks. Expect regulators to refine documentation expectations (rollback plans, verification evidence, controller-state telemetry) around this pathway.

## Cluster Enforcement and Supplier Control

[UNITED STATES](#) | [INTERNATIONAL](#)

Medline NAMIC RA syringe convenience-kit cluster closed at 4 Class I downstream packagers (American Contract Systems, MAI, AVID Medical, Aligned Medical Solutions/Windstone) – originating Warning Letter to Medline March 25 ([FDA recall page](#)). IMDRF opens public consultation on Supplier Control Guidance ([IMDRF](#)).

**6–12 month outlook:** Supplier-component vigilance triggers, downstream packager mapping, and traceability through convenience-kit assembly will become standard regulator expectations. The NAMIC cluster has set the template; IMDRF's draft formalizes it across jurisdictions. Sponsors should re-test PMS clustering logic against shared-component scenarios this cycle.

## Methodology

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Weekly mode covering May 18 – May 24, 2026. 45 highest-signal sources monitored across North America, EU / EFTA / UK, Asia-Pacific, ASEAN, GCC / Middle East, Latin America, EAEU, international harmonization (IMDRF, WHO, MDSAP), standards (ISO TC 210, IEC TC 62, AAMI), Notified Bodies (BSI, TUV SUD), and cross-cutting (CISA medical device advisories, WTO TBT device-related). Items classified into CRITICAL (framework-level / policy-triggering), STRATEGIC (durable regulatory impact), and MONITOR (individual operational or vigilance events tracked for awareness). Scope strictly filtered to medical devices (all classes), in vitro diagnostics, Software as a Medical Device including AI/ML and digital-health apps, and the device-side of drug-device combinations. Pure pharmaceuticals, biologics, vaccines, cosmetics, veterinary devices, food/supplements, and generic chemical regulations are excluded. Every CRITICAL/STRATEGIC claim cross-checked against a primary regulator URL before inclusion; secondary commentary cited by name only.

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