ASPHALION MedTech

NEWS-LETTER

Regulatory updates
Q3 2026 (June 2026-September 2026)

EU

RoW

New Standard on Risk Management for Machine Learning-Enabled Medical Devices

Date: June 2026
Topic / product area: Artificial intelligence, machine learning, risk management, ISO 14971

Summary:

ISO published the first edition of ISO/TS 24971-2:2026, providing guidance on AI- and machine learning-specific risks and on applying ISO 14971 to machine learning-enabled medical devices. It is intended for use together with ISO 14971 and ISO/TR 24971. Large language models and generative AI are expressly outside its scope.

Why it matters/ practical impact:

Manufacturers should assess whether their risk management files adequately address machine learning-specific issues throughout development, validation, deployment, monitoring and change control. A documented gap assessment should confirm product scope, identify any additional hazards and risk controls, and ensure that production and post-production monitoring can detect changes in model performance and emerging risks

Reference links:
ISO/TS 24971-2:2026

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SWISSDAMED Registration Becomes Mandatory for Medical Devices and IVDs

CH

Date: July 2026
Topic / product area: Device registration, UDI, market access, medical devices, IVDs

Summary:

From 1 July 2026, manufacturers and authorised representatives must register devices, systems and procedure packs placed on the Swiss market in the swissdamed UDI Devices module. This new procedure replaces the existing notification procedures. Devices placed on the market after 1 July benefit from a transitional period until 31 December 2026, while devices associated with serious incidents, field safety corrective actions or trend reports must be registered without a transitional period.

Certain categories remain subject to form-based notification, including repackaged or relabelled devices, DEVIT products, in-house devices and custom-made devices.

Why it matters/ practical impact:

Manufacturers and Swiss authorised representatives should map their Swiss portfolios, confirm responsibility for registration and complete the required records within the applicable deadline. Registration fees are CHF 200 for the first UDI-DI and CHF 20 for each additional UDI-DI with the status “On the market”, subject to a CHF 10,000 annual ceiling. The first invoices will be issued from January 2027 and will retrospectively include devices already registered by then.

Reference links:
SWISSDAMED

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Updated Standard Fee Lists Improve Visibility of MDR and IVDR Conformity Assessment Costs

EU

Date: 13 July 2026
Topic / product area: Notified bodies, conformity assessment, certification costs, MDR/IVDR

Summary:

The European Commission published an updated compilation of the standard fees made publicly available by notified bodies designated under Regulations (EU) 2017/745 and (EU) 2017/746. The publication supports the transparency requirements established in Article 50 MDR and Article 46 IVDR and offers manufacturers a central point from which to identify and compare the fee information published by notified bodies.

Why it matters/ practical impact:

Manufacturers and sponsors can use the updated information when planning certification and surveillance budgets, assessing notified-body proposals and anticipating lifecycle costs. However, the published standard fees should not be interpreted as a complete quotation. The final cost may also depend on device complexity, classification, technical-documentation quality, number of sites, audit duration, sampling, clinical or performance-evaluation requirements and the need for expert-panel or laboratory involvement.

Reference link:
Updated list of notified bodies' standard fees

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Dashboard 3.5 Expands the Evidence Base for Monitoring Device Availability in the EU

EU

Date: 14 July 2026
Topic / product area: Market availability, MDR/IVDR transition, certification capacity, notified bodies

Summary:

The European Commission published version 3.5 of the dashboard developed under the study supporting the monitoring of medical device availability in the EU market. The dashboard consolidates information collected from notified bodies, manufacturers, authorised representatives and healthcare stakeholders to provide an updated view of certification activity and market availability under the MDR and IVDR.

Why it matters/ practical impact:

The dashboard can help manufacturers benchmark broader certification trends, identify potential capacity constraints and support regulatory planning for portfolios that remain in transition. It is also relevant for strategic discussions on possible shortages, discontinuations and the practical effects of MDR and IVDR implementation. Companies should nevertheless avoid using aggregated dashboard data as a substitute for product-specific transition planning, notified-body engagement or supply-continuity assessment.

Reference links:
Study supporting the monitoring of availability of medical devices on the EU market

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MDCG 2026-5 Clarifies UDI Responsibilities When Distributors Relabel or Repackage Devices

EU

Date: 22 July 2026
Topic / product area: UDI, relabelling, repackaging, distributors, manufacturers, Articles 16 MDR/IVDR

Summary:

The Medical Device Coordination Group published MDCG 2026-5, a position paper addressing UDI assignment where distributors carry out relabelling or repackaging activities. The document clarifies how UDI responsibilities should be handled when activities performed by a distributor affect the device label or packaging and when those activities may trigger manufacturer obligations under the MDR or IVDR.

Why it matters/ practical impact:

Manufacturers and distributors should review their Article 16 arrangements, quality agreements and labelling workflows to confirm who controls the UDI-DI, how changes are assessed and whether a new UDI-DI is required. Particular attention should be given to language changes, pack-size changes, repackaging configurations and any modification that could affect identification or traceability. Procedures should also ensure consistency between the physical label, EUDAMED data, certificates and distribution records.

Reference link:
MDCG 2026-5 MDCG Position Paper

AEMPS Enables Prior Notification of In-House IVD Manufacturing in Spain

ES

Date: 23 July 2026
Topic / product area: In-house IVDs, health institutions, Article 5(5) IVDR, Real Decreto 942/2025

Summary:

The Spanish Agency of Medicines and Medical Devices, AEMPS, established a transitional procedure allowing Spanish health institutions that manufacture and use in-house IVDs to submit the prior notification required by Article 9.8 of Real Decreto 942/2025. The simplified procedure will apply until the dedicated electronic application becomes available. AEMPS also confirmed that the current requirements of Article 5(5) IVDR and the national legislation remain applicable while the proposed amendment of the IVDR is still under negotiation.

Why it matters/ practical impact:

Spanish health institutions manufacturing in-house IVDs should determine whether their activities fall within the scope of the notification requirement and should not postpone compliance while awaiting possible future changes to the IVDR. They should maintain evidence supporting the health-institution exemption, including justification of unmet patient needs, manufacturing and performance documentation, risk management, quality-system controls and public declarations where applicable. AEMPS also recommends initiating accreditation activities in accordance with ISO 15189 to facilitate alignment with the applicable requirements.

Reference link:
AEMPS

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ISO 10993-3:2026 Shifts the Focus from Testing to Risk-Based Evaluation

Date: August 2026
Topic / product area: Biological evaluation, genotoxicity, carcinogenicity, reproductive and developmental toxicity

Summary:

ISO published the fourth edition of ISO 10993-3, covering the evaluation of genotoxicity, carcinogenicity, reproductive toxicity and developmental toxicity. The revised standard places greater emphasis on a risk-based evaluation strategy that considers intended use, nature and duration of exposure, chemical characterisation and toxicological assessment before determining whether additional biological testing is necessary. It also incorporates genotoxicity test-method guidance previously addressed in ISO/TR 10993-33.

Why it matters/ practical impact:

Manufacturers should assess whether existing biological evaluation plans and reports remain aligned with the revised standard. The update may affect the scientific justification for endpoint selection, the use of chemical and toxicological data, testing strategies and the rationale for waiving tests. The publication of a new ISO edition does not automatically establish harmonised-standard status in the EU, so manufacturers should distinguish between the current state of the art and formal citation in the Official Journal of the European Union.

Reference links:
ISO 10993-3:2026

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MDCG 2020-16 Rev.5 Updates the Interpretation and Examples for IVDR Rule 7

EU

Date: 9 September 2026
Topic / product area: IVD classification, Rule 7, class B devices, IVDR

Summary:

The MDCG published revision 5 of MDCG 2020-16, the guidance on classification rules for IVDs under Regulation (EU) 2017/746. The revision clarifies the rationale for Rule 7 and updates its examples. Under Rule 7, controls without a quantitative or qualitative assigned value are classified as class B. The revised guidance further explains that these controls are not assigned a value because the expected result is established by the user and is not defined by the manufacturer.

Why it matters/ practical impact:

Manufacturers of IVD controls should verify whether a quantitative or qualitative value is assigned by the manufacturer, as this distinction determines whether Rule 7 applies. Controls without an assigned value fall within class B under Rule 7, while controls with manufacturer-assigned values must be classified according to the rule applicable to the analyte or intended examination they control. Manufacturers should review intended purposes, labels, instructions for use and classification rationales to ensure that the assigned-value status is clearly defined and consistently documented.

Reference link:
MDCG 2020-16 rev.5

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REGULATORY SPOTLIGHT

WHEN DOES AN AI TRANSCRIPTION AGENT BECOME MEDICAL DEVICE SOFTWARE?

AI-enabled transcription agents are increasingly used in healthcare to capture clinical conversations, produce summaries and structure information for the electronic health record. Their regulatory status does not depend solely on the technology used or on their deployment in a healthcare environment. The decisive elements are the manufacturer's intended purpose, the functions performed and the impact of the output on diagnosis, treatment or other clinical decisions.

A tool limited to faithful transcription, administrative formatting or documentation support may fall outside the definition of medical device software if it does not provide information for a medical purpose. The regulatory position can change when the system interprets clinical information, prioritises findings, proposes diagnoses or treatments, generates alerts, recommends actions or otherwise provides information used to make decisions for individual patients.

Where the software has a medical purpose, classification under Rule 11 of Annex VIII MDR should be assessed. Software providing information used to make diagnostic or therapeutic decisions is generally class IIa, with escalation to class IIb or class III where an incorrect decision may cause serious deterioration, surgery, irreversible deterioration or death. The assessment should be based on the complete intended workflow rather than the label 'transcription agent'.

The key regulatory question is not whether a system uses generative AI, but what the manufacturer intends the system to do and how its output influences patient care. Early qualification and classification analysis can prevent late redesign, incorrect procurement assumptions and gaps in clinical, quality and post-market evidence.

Reference link:
IASNS

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UPCOMING EVENTS

6 - 9 OCT

CPHI

📍 **Milan**

Hall 14 · Booth 14D68

29-30 OCT

TEAM PRRC ANNUAL SUMMIT

📍 **Prague**

ATTENDING

16-19 NOV

MEDICA

📍 **Düsseldorf**

BOOTH 17D04

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