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NEWS-LETTER

Regulatory updates –
Q1 2026 (December 2025-March 2026)

EU Launches Breakthrough Device (BtX) Framework: Accelerated Pathways for High-Innovation Medical Technologies.

EU

Date: December 2025
Topic / product area: Clinical evaluation / Performance evaluation, Notified Bodies, AI / Cybersecurity, Software.

Summary: The Medical Device Coordination Group (MDCG) has released comprehensive guidance on the Breakthrough Device (BtX) designation under the MDR and IVDR. A BtX is defined as an innovation offering a novel diagnostic or therapeutic option for serious, life-threatening, or irreversibly debilitating conditions that addresses an unmet medical need compared to the current state of the art. To support this initiative, the European Medicines Agency (EMA) has launched a pilot programme as of 28 April 2026, offering a structured pathway for developers to receive expert panel support. Information on how to apply can be found at this link.

Why it matters/ practical impact: To qualify for this status, a device must meet two cumulative criteria:
• High Degree of Novelty: The technology, clinical procedure, or application must significantly differ from established history; incremental or iterative improvements to existing devices are generally insufficient for designation.
• Significant Positive Clinical Impact: The manufacturer must demonstrate a reasonable expectation that the device will improve patient outcomes (e.g., reduced mortality or morbidity) for life-threatening or irreversibly debilitating conditions.
Advantages of BtX Designation: Once designated, manufacturers gain access to several high-value benefits designed to reduce time-to-market:
• Priority Scientific Advice: Earlier and prioritised access to EMA Expert Panels for clinical development strategies.
• Prioritised Conformity Assessment: Notified Bodies are encouraged to prioritise BtX files and engage in "structured dialogues" to clarify evidence expectations early on.
• Flexibility in Clinical Evidence: In cases of high unmet need, devices may be placed on the market with a higher level of uncertainty, provided there is a robust plan for "milestone-based" post-market data collection (PMCF/PMPF).
• SME Support: Proportionate fees and dedicated support mechanisms for smaller manufacturers.

Reference link
https://health.ec.europa.eu/document/download/edca94c7-62ab-4dd5-8539-2b347bd14809_en?filename=mdcg_2025-9.pdf

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MDCG Issues Comprehensive Guidance on Post-Market Surveillance (PMS) for Medical Devices and IVDs

EU

Date: December 2025
Topic / product area: PMS / PMCF / PMPF, Clinical evaluation / Performance evaluation, Notif Bodies, UDI / EUDAMED.

Summary: The Medical Device Coordination Group (MDCG) has released a pivotal guidance document to clarify the requirements for Post-Market Surveillance (PMS) under the MDR and IVDR. This document provides a structured framework for manufacturers to "plan, establish, document, implement, maintain, and update" a PMS system that is integral to their overall Quality Management System (QMS). It outlines the mandatory elements of a PMS Plan, the methods for active data collection, and the procedures for reporting via PMS Reports (for lower-risk devices) or Periodic Safety Update Reports (PSURs) for higher-risk categories.

Why it matters/ practical impact: This guidance reinforces the shift from passive complaint monitoring to a "proactive" approach, where manufacturers are explicitly obligated to actively seek out information from various sources, such as customer surveys, scientific literature, and clinical registries. Practically, this means manufacturers must ensure a seamless interface between PMS data and other key QMS processes. Specifically, real-world data must be used to continuously update risk management files, clinical evaluations, and the Summary of Safety and Clinical Performance (SSCP) to ensure the benefit-risk ratio remains acceptable throughout the device's entire lifetime. For manufacturers of custom-made devices, the guidance also clarifies that they are not exempt from establishing a formal PMS system and plan.

Reference link
https://health.ec.europa.eu/document/download/edca94c7-62ab-4dd5-8539-2b347bd14809_en?filename=mdcg_2025-9.pdf

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Regulatory updates –
Q1 2026 (December 2025-March 2026)

Commission Proposes Landmark Revision to Simplify MDR and IVDR and Reduce Administrative Burden

EU

Date: December 2025
Topic / product area: Notified Bodies, Clinical evaluation / Performance evaluation, PMS / PMCF / PMPF

Summary: The European Commission has published a significant proposal to amend Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR). This initiative aims to address structural issues in the current framework by simplifying certification rules, broadening the definition of acceptable clinical data, and introducing more proportionate requirements for well-established technologies. Key changes include the removal of the mandatory five-year expiration for certificates, replaced by risk-based periodic reviews, and a more flexible approach to equivalence for clinical evaluations.

Why it matters/ practical impact: First and foremost, it should be considered that this text is still a proposal, so far none of the changes proposed shall be considered as effective. This revision represents a major shift towards a leaner, more cost-effective regulatory environment, with estimated industry savings of over €3 billion per year. For manufacturers, the most immediate impacts include reduced frequency for Periodic Safety Update Reports (PSURs), the removal of the five-year recertification hurdle, and streamlined validation for Summaries of Safety and Clinical Performance (SSCP). SMEs will benefit from reduced Notified Body fees and more flexible requirements for the Person Responsible for Regulatory Compliance (PRRC). Furthermore, the introduction of priority pathways for breakthrough and orphan devices will significantly accelerate market access for high-impact medical innovations.

Reference link
https://health.ec.europa.eu/publications/proposal-regulation-simplify-rules-medical-and-vitro-diagnostic-devices_en

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Regulatory updates –
Q1 2026 (December 2025-March 2026)

Harmonized Standards Update

EU

Date: January 2026
Topic / product area: Standards

Summary: The European Commission has updated the lists of harmonised standards for both the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR). These updates reflect technical progress and the need to support the specific requirements of Regulations (EU) 2017/745 and (EU) 2017/746.
Under Decision (EU) 2026/193 (MDR), the following updates have been introduced:

- New entries: EN ISO 7197:2024 (neurosurgical implants), EN ISO 14630:2024 (non-active implants), EN ISO 17665:2024 (sterilisation), EN ISO 18562 series (parts 1-4, breathing gas pathways), EN ISO 21535:2024 (hip-joint replacements), EN ISO 21536:2024 (knee-joint replacements), and EN ISO 80369-2:2024 (small-bore connectors).
- Modifications: EN ISO 10993-4:2017/A1:2025 (blood interactions) and EN ISO 14155:2020/A11:2024 (good clinical practice).

Under Decision (EU) 2026/197 (IVDR), the update includes:
New entries: EN ISO 17665:2024 (sterilisation) and the EN ISO 18113 series (parts 1-5, information supplied by the manufacturer/labelling for professional and self-testing use).

Why it matters/ practical impact: Adhering to these specific standards grants manufacturers a presumption of conformity with the General Safety and Performance Requirements (GSPR) they cover. Practical consequences include:

- Updated Documentation: Manufacturers must update their EU Declaration of Conformity and technical files to reference these latest versions.
- Clinical Rigour: The modification to EN ISO 14155 is particularly critical for clinical investigations, as it aligns the standard with current Good Clinical Practice expectations under the MDR.
- Market Access for IVDs: The harmonisation of the EN ISO 18113 series provides a definitive benchmark for labelling and instructions for use (IFU), which is a frequent point of scrutiny during Notified Body audits.
- Sterilisation Alignment: The inclusion of EN ISO 17665:2024 in both decisions provides a harmonised approach to moist heat sterilisation across the entire medical technology sector.

Reference link: https://eur-lex.europa.eu/eli/dec_impl/2026/193/oj
https://eur-lex.europa.eu/eli/dec_impl/2026/197/oj

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Royal Decree 90/2026: A New Framework for Medical Device Financing and Pricing

ES

Date: February 2026
Topic / product area: National requirements

Summary: The Spanish government has officially published Royal Decree 90/2026, which replaces the nearly 30-year-old RD 9/1996. This landmark regulation establishes a modernised, electronic-only procedure for the inclusion, price setting, and exclusion of medical devices within the National Health System (SNS) pharmaceutical benefit for non-hospitalised patients . It covers critical product categories such as wound dressings, drug delivery systems, ostomy and incontinence products, and devices for protecting or reducing internal lesions. The decree introduces a Maximum Industrial Price (PVL) system and defines specific commercial margins for distributors and pharmacies.

Why it matters/ practical impact: This decree provides a much-needed clear administrative path for public reimbursement in Spain, ending decades of regulatory ambiguity. For manufacturers, the impact is significant: all applications must now include detailed economic and clinical justifications, price comparisons with other EU member states, and a three-year sales forecast. Crucially, the regulation introduces "homogeneous groups" and "lowest prices", which will empower pharmacists to substitute prescribed products with the lowest-priced equivalent, dramatically increasing market competition. Additionally, manufacturers must adapt their secondary packaging to incorporate a newly designed, high-security "cupón precinto" (voucher) to identify financed products.
The established commercial margins—6% for distributors and 21% for pharmacies for products with a PVL up to €59—provide financial predictability but may require existing manufacturers to request price revisions during the specified transitional periods starting in July 2026.

Reference link: https://www.boe.es/diario_boe/txt.php?id=BOE-A-2026-3215

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Q1 2026 (December 2025-March 2026)

ISO Updates: New 2026 Editions for Good Clinical Practice and Manufacturer Information

EU

RoW

Date: March 2026
Topic / product area: Standards

Summary: ISO has released two foundational updates for the medical device sector: the fourth edition of ISO 14155 on Good Clinical Practice (GCP) and the second edition of ISO 20417 regarding manufacturer-supplied information. ISO 14155:2026 specifies GCP for the design, conduct, and reporting of clinical investigations to assess device safety and performance, now including explicit requirements for Software as a Medical Device (SaMD) regarding analytical and scientific validity. Concurrently, ISO 20417:2026 replaces the 2021 version, establishing a revised framework for labelling, packaging, and Instructions for Use (IFU) while introducing the new concept of "applicable policy".

Why it matters/ practical impact: These standards are essential for defining an updated regulatory state of the art under the MDR. The update to ISO 14155 ensures the scientific credibility of clinical data and protects subject well-being, which is critical for successful conformity assessments. SaMD developers must now carefully justify any exemptions from these GCP requirements, particularly regarding indirect subject contact. Yet, it shall be considered that current harmonized version under MDR corresponds to EN ISO 14155:2020/A11:2024.
Regarding ISO 20417:2026, the focus on clear and consistent labelling across different jurisdictions facilitates global regulatory compliance and improved traceability. Practically, manufacturers must ensure their clinical trial protocols and technical documentation for labelling are updated to these 2026 versions to avoid non-conformities during Notified Body audits. These combined updates reinforce the necessity of integrating risk management with both clinical evidence and the information provided to the end-user.

Reference link: https://www.iso.org/es/norma/20417
https://www.iso.org/standard/83968.html

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Regulatory updates –
Q1 2026 (December 2025-March 2026)

EU Commission Expands List of Well-Established Technologies (WET) Exempt from Clinical Investigations

EU

Date: March 2026
Topic / product area: Clinical evaluation / Performance evaluation

Summary: The European Commission has adopted a Delegated Regulation amending Article 61(6)(b) of the MDR (EU) 2017/745 to significantly expand the list of implantable and Class III devices exempt from the obligation to perform clinical investigations. These devices are classified as Well Established Technologies (WET), meaning they possess simple and stable designs, well-known safety and clinical performance characteristics, and a long history of use on the Union market. The expanded list now includes a wide range of products, including dental implants, orthodontic devices, various catheters (e.g., atrioseptostomy balloon, port, and anticoagulant-coated catheters), guidewires, spinal posterior fixations, and bone fillers.

Why it matters/ practical impact: This is a major development for manufacturers of high-risk devices that have long been considered the "standard of care" with little evolution in their state of the art. The exemption reduces the administrative and financial burden of conducting new clinical investigations for technologies where safety is already well-proven. However, it is vital to note that this is not a total exemption from clinical requirements; manufacturers must still conduct and document a clinical evaluation based on sufficient clinical data and comply with any relevant product-specific Common Specifications (CS). This amendment provides a much-needed pragmatic pathway for maintaining mature, essential medical devices on the EU market while ensuring high safety standards.

Reference link: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=PI_COM%3AC%282026%291798

ASPHALION MedTech NEWS-LETTER

REGULATORY SPOTLIGHT

THE MYTH: "IF A SOFTWARE ERROR CAN HARM A PATIENT, IT'S A MEDICAL DEVICE."

It sounds intuitive, doesn't it? Many developers and clinicians operate under the assumption that if a software program is used in a healthcare setting and a bug or data glitch could lead to clinical harm, the software must be regulated as a **Medical Device (MDR)** or an **In Vitro Diagnostic (IVDR)**.
The Reality? Impact does not equal Qualification.
Consider a Hospital Information System (HIS) or an Electronic Health Record (EHR). If these systems malfunction and swap the records of two patients, the clinical consequences could be catastrophic. However, these platforms are generally not medical devices. Why? Because their intended purpose is the storage, archiving, and transmission of data, rather than a specific medical intervention.

The Regulatory Compass: MDCG 2019-11

To move beyond intuition and into compliance, we must look at the definitions within **Regulation (EU) 2017/745 (MDR)** and **2017/746 (IVDR)**, supplemented by the essential guidance document **MDCG 2019-11.**
Qualification isn't about "what could go wrong"; it's about **what the software is intended to do**.
To determine if your software (MDSW) falls under the regulatory umbrella, you must ask three critical questions:
Is there a specific medical purpose? Does it diagnose, prevent, monitor, treat, or alleviate a disease or condition?
Does it do more than just "handle" data? If the software's action is limited to storage, archival, lossless compression, or simple communication (search/fetch), it likely stays in the "lifestyle" or "administrative" zone.
Is there an individualised clinical benefit? Does the software create new information for a specific patient that helps a clinician make a decision?
Key Distinction: If your software takes patient data and performs a calculation or uses an algorithm to provide a diagnosis or treatment recommendation, you are likely looking at a Medical Device. If it simply displays a PDF of a lab result, you are likely not.
The Takeaway
Before you commit to a complex (and expensive) regulatory pathway—or conversely, before you accidentally launch an unregulated device—remember these three pillars:
Purpose over Risk: Risk determines the Class (I, IIa, IIb, III), but Intended Purpose determines the Qualification.
Read the Guidance: Always benchmark your software against the decision steps in MDCG 2019-11.

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UPCOMING EVENTS

5-8 MAY

RAPS Euro Convergence

BOOTH 27
RAPS Euroconvergence
Lisbon

11-13 MAY

THE MEDTECH FORUM 2026

ATTENDING
The MedTech Forum
Copenhague

27-28 MAY

health revolution congress

BOOTH
Health Revolution Congress
Barcelona

4 JUNE

ATTENDING
32 Encuentro Sector Tecnología Sanitaria FENIN
Madrid

9-10 JUNE

BOOTH
European Medical Device Summit
Düsseldorf

29-30 OCT

TEAM-PRRC ANNUAL SUMMIT

ATTENDING
TEAM PRRC ANNUAL SUMMIT
Prague

16-19 NOV

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