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Regulatory updates
Q2 2026 (April 2026-June 2026)

Comprehensive Update to EU Guidance: New Borderline Manual and Revised Classification Guidelines Released

EU

Date: April 2026
Topic / product area: Borderline products, Software, Substance-based devices

Summary:

The MDCG has simultaneously released two cornerstone documents for the sector: Version 5 of the Manual on Borderline and Classification and a significant Revision 1 of the MDCG 2021-24 Guidance on Classification. The Manual records new agreements reached under the Helsinki Procedure, providing specific qualification outcomes for complex products such as COVID-19 antibody sprays, root canal irrigation solutions, and medical calculators. In parallel, the updated Classification Guidance (MDCG 2021-24) introduces structural explanatory changes to Rule 9 (active devices) and provides updated practical notes for Rules 2, 8, 10, 12, 16, and 22, incorporating lessons learned since the initial MDR implementation.

Why it matters/ practical impact:

These updates provide much-needed legal certainty for manufacturers operating in "grey zones." The Manual clarifies that new borderline products examples like:

- 1.1.9.7 Device used intended to administer a medicinal product (Other medical device borderlines).
- 1.2.1.2 Penis holster (Classification MDs - Rule 1).
- 1.2.3.1 Syringe containing glass beads (Classification MDs - Rule 3).
- 1.2.6.1 Needles for root canal irrigation (Classification MDs - Rule 6).
- 1.2.21. Saline solutions for nasal irrigation (Classification MDs - Rule 21).

Reference links:
MDCG 2021-24 Rev.1
Manual on borderline

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MDCG Releases Update to EMDN Guidance: Focus on EUDAMED Integration and Maintenance

EU

Date: April 2026
Topic / product area: Nomenclature

Summary: The Medical Device Coordination Group (MDCG) has published the second revision of the European Medical Device Nomenclature (EMDN) FAQ. This nomenclature is the cornerstone for device registration in EUDAMED, where it is associated with each Unique Device Identifier (UDI-DI). The updated guidance clarifies the seven-level alphanumeric hierarchical structure—comprising Categories, Groups, and Types—and provides detailed instructions on code assignment for devices with multiple intended purposes, including those listed in Annex XVI (products without a medical purpose). It also outlines the annual review procedure and how changes to the nomenclature are communicated to stakeholders.

Why it matters/ practical impact:

For manufacturers, selecting the correct EMDN code is not a "set and forget" administrative task; it is a critical regulatory requirement that impacts technical documentation, vigilance, and Notified Body sampling. Key takeaways include:

- Granularity is Mandatory: Manufacturers must always assign the most granular and terminal code available in the hierarchy.
- Code "99" Scrutiny: While the "99" extension (Others) can be used if no specific term fits, these codes are now subject to additional scrutiny during annual reviews to determine if a new, specific code is required.
- Annual Maintenance: Manufacturers should establish a standard practice to review the EMDN every January. Any changes (split or obsolete codes) must be reflected in technical files, certificates, and EUDAMED at the latest prior to the next annual surveillance audit.
- Obsolescence Policy: Codes rendered "obsolete" will remain visible in EUDAMED for five years to match maximum certificate lifespans, but they cannot be used for new registrations or updates to existing ones.

Reference links:

MDCG 2021-12 rev.2
MDCG 2026-1
MDCG 2026-2
MDCG 2026-3

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Team-NB Guidelines on Clinical Evaluation Based on Non-Clinical Data (Article 61.10).

EU

Date: 21 April 2026
Topic / product area: Clinical evaluation / Performance evaluation, Notified Bodies, Software

Summary: The European Association of Medical Devices Notified Bodies (Team-NB) has released a comprehensive position paper clarifying the application of Article 61(10) of the MDR. This article allows manufacturers of specific non-implantable devices (Class I, IIa, and IIb) to base their clinical evaluation on non-clinical data when the demonstration of conformity based on clinical data is deemed "not appropriate". The guidance outlines the strict criteria Notified Bodies (NBs) use to assess these justifications, focusing on intended performance, device-body interaction, and risk management results.

Why it matters/ practical impact: This paper provides a vital roadmap for manufacturers of legacy or low-risk technologies to avoid unnecessary clinical trials while maintaining compliance. Key practical takeaways include:

- Interaction Beyond Contact: NBs now clarify that interaction is not limited to physical contact; for instance, Software (SaMD) interacting with cognitive processes must provide a robust justification if clinical data is omitted.
- The "Claim" Trap: Article 61(10) is inapplicable if the manufacturer makes any explicit clinical claims (e.g., "reduces pain") or if the state-of-the-art safety endpoints are fundamentally defined by clinical data.
- Invasiveness: The more invasive a device or the more sensitive the tissue it interacts with, the less likely a NB will accept a non-clinical justification.
- Full Documentation Still Required: Devices under Article 61(10) are not exempt from the clinical evaluation process; they still require a complete Clinical Evaluation Report (CER) and active Post-Market Clinical Follow-up (PMCF) plans to monitor real-world safety.

Reference link:
Team-NB Position Paper on Article 61.10.

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AI Act Integration: Classification and Guidelines for High-Risk Medical Device Software (MDAI)

EU

Date: 19 May 2026
Topic / product area: AI / Cybersecurity, Software, Notified Bodies

Summary: MDCG 2025-6 clarifies that medical device software incorporating Artificial Intelligence (MDAI) is subject to the AI Act (AIA). Under AIA Article 6(1), MDAI is automatically classified as "high-risk" if the device requires a third-party conformity assessment by a Notified Body (covering most devices from Class IIa and above, as well as specific Class I sterile or measuring devices).
Recent draft Commission guidelines further specify that AI systems used for healthcare triage or those materially influencing decisions regarding natural persons are generally high-risk, while those performing "narrow procedural tasks" (like noise reduction or neutral transcription) may be exempted via the "filter mechanism" in Article 6(3).

Why it matters/ practical impact: Manufacturers must integrate AIA requirements—such as data governance, logging, robustness, and human oversight—into their existing MDR/IVDR Quality Management Systems and Technical Documentation. The classification of MDAI as high-risk under the AIA does not change its MDR/IVDR risk class but adds significant horizontal regulatory requirements and oversight.

Reference links:
MDCG 2025-6
Commission Draft AI Guidelines (May 2026)

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Mandatory EUDAMED Deadlines: Approaching Transition for Existing Devices

EU

Date: 28 May 2026
Topic / product area: UDI/ EUDAMED

Summary: Following the functionality notice of the EUDAMED "Actors," "UDI and Devices," "Notified Bodies and Certificates," and "Market Surveillance" modules, mandatory registration timelines are now strictly defined. For products certified under MDR or IVDR before 28 May 2026, a transitional period exists that expires on 28 November 2026.

Why it matters/ practical impact: Manufacturers must act immediately to ensure all devices in their portfolio are registered by the November deadline. Crucially, any device certified after 28 May 2026 must be registered in EUDAMED before it can be lawfully placed on the market. Failure to meet these deadlines may result in commercialisation delays and market surveillance findings.

Reference link:
EUDAMED Overview

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RoW

Publication of ISO 10993-7:2026: Strengthening EO Sterilisation Residual Requirements

Date: June 2026
Topic / product area: Substance-based devices, Clinical evaluation / Performance evaluation

Summary: The third edition of ISO 10993-7 has been published, representing the most significant update to Ethylene Oxide (EO) and Ethylene Chlorohydrin (ECH) sterilisation residual requirements in nearly two decades.
Formally superseding the 2008 version and its 2019 amendment, this edition moves away from default allowable limits for a standard 70kg adult. It introduces a single, coherent framework focused on risk-based limits tailored to specific patient populations, with enhanced safeguards for the most vulnerable individuals.

Why it matters/ practical impact: For manufacturers using EO sterilisation, this update necessitates an immediate review of their technical documentation. Key practical consequences include:

- Vulnerable Patients: Manufacturers must now provide specific attention and limits for neonates, infants, pregnant women, and immunocompromised patients.
- Existing limits based on the old 2008 standard may no longer be considered protective for these groups.
- Mandatory Toxicological Assessment: Relying on default tabulated values is no longer sufficient. Every manufacturer must now provide a documented toxicological risk assessment explicitly linking residual limits to the intended use, clinical context, and patient population.
- Batch Release Rigour: The standard provides structured expectations for batch release, detailing the use of residual dissipation data and mandatory aeration profiles.

Coordinated Documentation Update: Manufacturers should conduct a gap assessment immediately. Any changes will have downstream effects on the overall biological evaluation (ISO 10993-1) and the risk management file (ISO 14971).

Reference link:
ISO 10993-7:2026

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RECOPS launch: New Mandatory Commercialisation Registry for Medical Devices

Date: June 15 2026
Topic / product area: UDI / EUDAMED / Registers

Summary: The Spanish Medicines Agency (AEMPS) has implemented RECOPS, a mandatory electronic registry for all economic operators commercialising medical devices and IVDs (except custom-made) in Spain. The system is linked to EUDAMED, automatically downloading product, manufacturer, and certificate data once they are visible in the European database. However, manufacturers must manually provide additional information, including the specific Spanish labelling and IFU, and the actual date the commercialisation begins in Spain.

Why it matters/ practical impact: Every agent distributing products in Spain must be registered in RECOPS before commercialisation begins. For devices already on the market before 28 May 2026, there is a transitional deadline of 28 November 2026 to complete registration. The system allows for "associations," enabling distributors to use documentation already uploaded by another authorised economic operator, though each agent must still perform their own notification.

Reference links:
RECOPS Portal (AEMPS)
RECOPS tutorial provided by AEMPS

COMBINE Programme Launches Phase 2: Streamlined Assessments for Combined Studies

EU

Date: 17 June 2026
Topic / product area: Clinical evaluation / Performance evaluation, Combination products

Summary: The European Commission and Member States have launched Phase 2 of the COMBINE pilot for coordinated assessments of "combined studies" involving both medicinal products and medical devices or IVDs. This new phase expands the scope to include medicinal product trials combined with medical device investigations and certain IVD performance studies (including companion diagnostics).

Why it matters/ practical impact: The pilot introduces a more flexible "rolling process" with monthly opportunities to submit expressions of interest starting in late 2026. For manufacturers, this offers a streamlined, "all-in-one" administrative pathway, reducing the complexity of navigating simultaneous drug and device/IVD regulatory frameworks for clinical trials.

Reference link:
COMBINE project 1 pilot – Phase 2

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EU Commission Expands Lists of Well-Established Technologies (WET) Exemptions

EU

Date: 29 June 2026
Topic / product area: Clinical evaluation / Performance evaluation, Substance-based devices

Summary: The European Commission has published two significant amendments to the MDR expanding the categories of devices considered "well-established technologies". These devices are characterised by simple, stable designs and well-known safety and clinical performance profiles. The expanded lists include a variety of products such as specific catheters (atrioseptostomy balloon, anticoagulant-coated), dental implants, orthodontic devices, bone fillers, and spinal posterior fixations.

Why it matters/ practical impact: These exemptions provide a pragmatic regulatory pathway by reducing the compliance burden for mature technologies. Specifically, certain Class IIb implantable devices are now exempt from individual technical documentation assessments, and specific Class III and implantable devices are exempt from the mandatory clinical investigation requirement, provided their clinical evaluation is based on sufficient existing clinical data.

Reference links:
Delegated Regulation (EU) 2026/1359
Delegated Regulation (EU) 2026/1451.

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Team-NB Proposes Risk-Adaptive Surveillance Framework for MDR and IVDR

EU

Date: 30 June 2026
Topic / product area: Notified Bodies, PMS / PMCF / PMPF, Clinical evaluation / Performance evaluation

Summary: The European Association of Medical Devices Notified Bodies (Team-NB) has released two position papers proposing a "risk-adaptive surveillance" system. This proposal aims to support the European Commission's initiative to remove the five-year expiry for certificates by replacing recertification with risk-based periodic reviews. The framework introduces three levels of monitoring: initial/enhanced, medium, and reduced, with the level determined by objective indicators such as serious incidents, major non-conformities, and the effectiveness of corrective actions.

Why it matters/ practical impact: For manufacturers, this represents a shift towards "for-cause" and performance-based oversight. Manufacturers with a clean six-year compliance history may qualify for "reduced surveillance," while any significant safety or compliance trigger will result in immediate re-escalation to the "initial/enhanced" level. Practically, this will affect the frequency of surveillance audits (potentially extending them to every 24 months for low-risk scenarios), the intensity of technical documentation sampling, and the frequency of unannounced visits

Reference link:
Team-NB Position Papers: IVDR and MDR

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REGULATORY SPOTLIGHT

RECOPS: BEYOND REGISTRATION THE CHALLENGE OF MANAGING REGULATORY DATA

RECOPS marks a significant step in Spain's efforts to strengthen oversight of medical devices and IVDs, while further integrating national registration requirements with EUDAMED. For industry, however, the main challenge may not be registration itself, but the management of regulatory data. Because RECOPS relies on information already available in EUDAMED, manufacturers, authorised representatives, importers and other economic operators need closer coordination to ensure product records are complete, accurate and visible at the European level before a RECOPS notification can be completed.

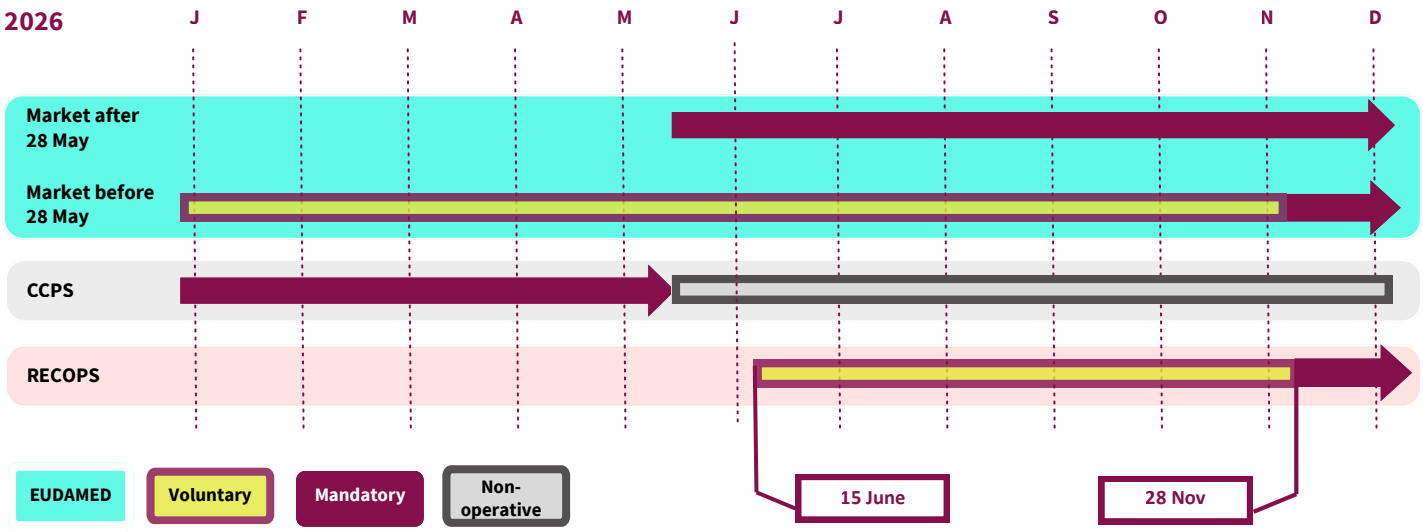
The impact is particularly significant for international companies and organisations managing large portfolios. RECOPS applies to economic operators commercialising devices in Spain, regardless of where they are established within the European Economic Area. For companies with hundreds or thousands of references, maintaining alignment between EUDAMED data, Spanish labelling, IFUs and commercialisation records may become a substantial operational task.

A further consideration concerns legacy registrations. Products previously notified through CCPS or RPS are not automatically transferred into RECOPS, requiring companies to actively review and reconcile existing portfolios within the new system.

RECOPS also reinforces the need for ongoing data maintenance. Regular updates, together with the applicable AEMPS fees associated with maintaining commercialisation records, highlight a broader trend across the sector: regulatory compliance is increasingly becoming a continuous data-governance activity rather than a one-off registration exercise.

The coming months will reveal whether RECOPS is viewed simply as a new national register or as a catalyst for more robust regulatory data management practices across the medical device industry.

EUDAMED and RECOPS Timelines



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UPCOMING EVENTS

SEPT

JAPAN

Tokyo & Osaka

ATTENDING diverse events

29-30 OCT

TEAM PRRC ANNUAL SUMMIT

Prague

ATTENDING

16-19 NOV

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