
Medical Device & *In Vitro* Diagnostic Medical Device Regulations – EU State of Play

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Agenda

- 1. Recent developments in the EU**
 - Breakthrough pathway & Pilot
 - Eudamed
 - Well-Established Tech
 - NB requirements
 - Digital
- 2. MDR / IVDR 2.0 (Commission proposal to revise MDR/IVDR)**



Recent developments in the EU



Breakthrough Technology Pathway Guidance & Pilot

Medical Device

Medical Device Coordination Group Document

MDCG 2025-9

MDCG 2025-9

**Guidance on Breakthrough Devices (BtX)
under Regulations 2017/745 & 2017/746**

December 2025

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission. The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

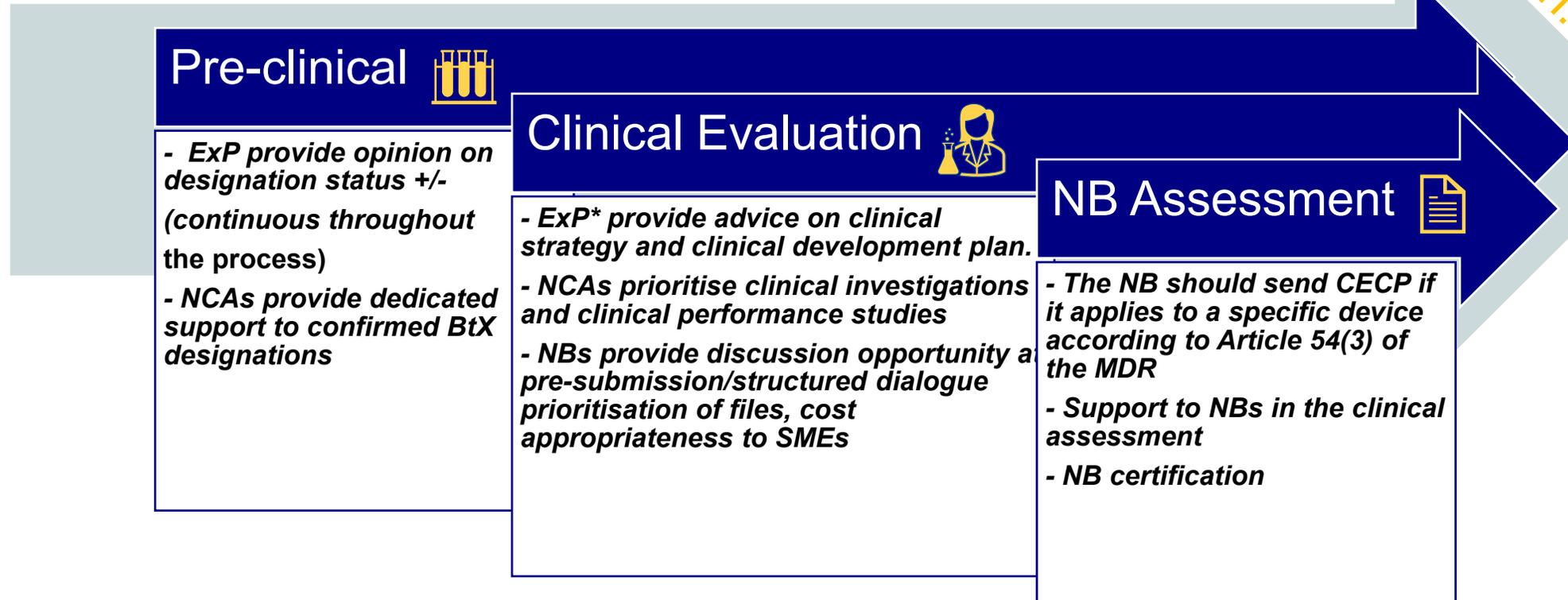
- Provides a **structured framework** for recognition and early regulatory support
- Assist manufacturers in navigating MDR/IVDR
- Improve **clarity and consistency** in regulatory interactions
- Support innovation **without introducing regulatory derogations**



Pilot launch: Q2 2026



Breakthrough Technology - Process



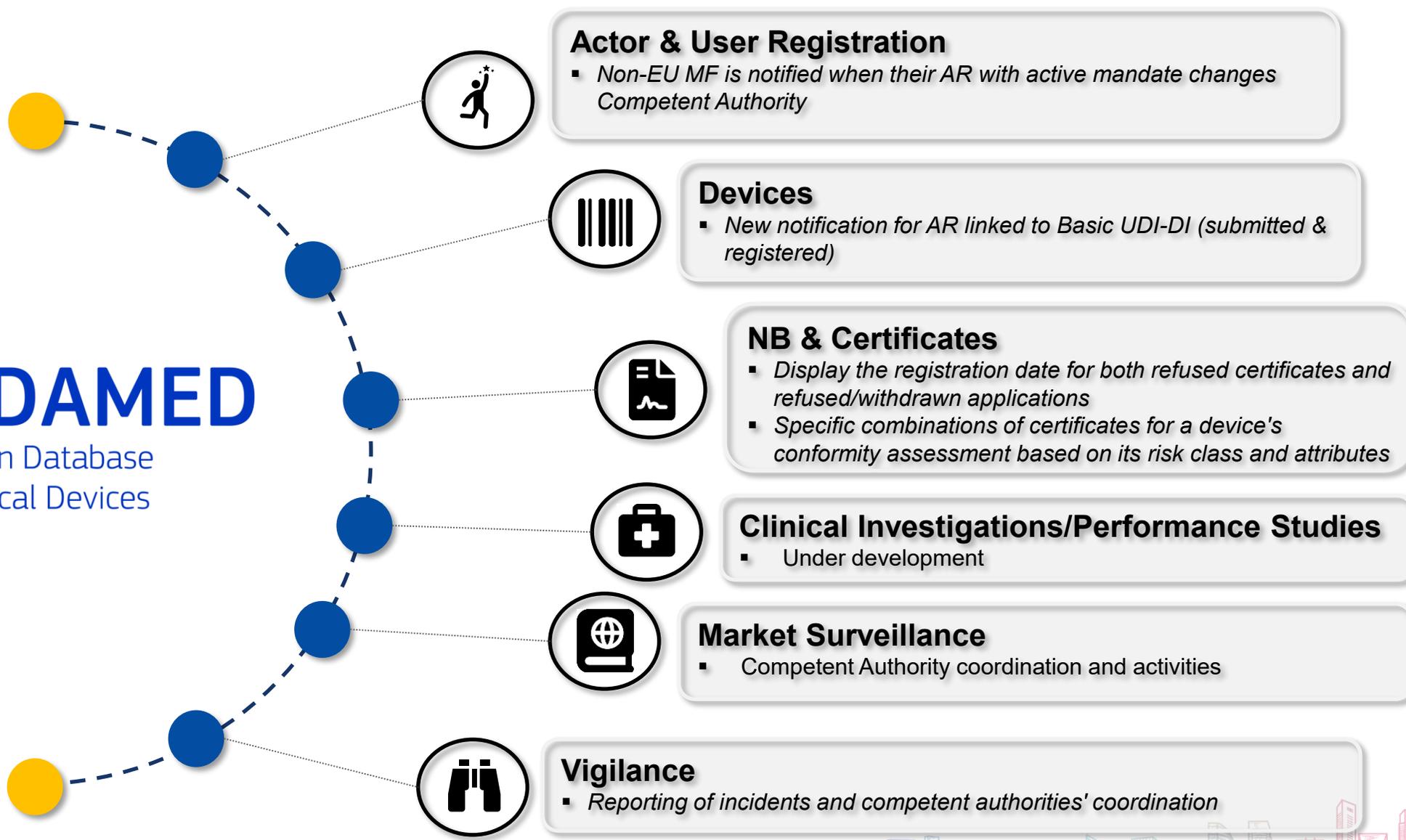
Concept & Discovery
TRL 1-3

Pre-clinical testing
TRL 4-5

Clinical Evaluation
TRL 5-6

Regulatory compliance / CE
TRL 7





List of key information which will be accessible in EUDAMED



All **manufacturers**, their **authorised representatives** and **importers**



All **devices**, the **core elements of the UDI database**, including the basic UDI and UDI-DI of devices,



Certificates of conformity, their scope and validity period,



List of notified bodies designated under the MDR, their identification numbers and their conformity assessment activities



The **summary of safety and clinical performance** reports for implantable devices and class III devices,



Scientific opinions of the expert panels and the written justification of the NB where it has not followed the scientific opinion of the expert panel,



Clinical investigation reports and their summary,



Manufacturer incident reports (partial access) and the **field safety notices** for Vigilance activities,



Summary of the results of market surveillance activities on their national territory by each EU Member State.



Well- Established Tech (WET)

Notified Body Requirements (Annex VII)



Expanding the list of Well-Established Technologies, which will have an impact on Article 18(3) – Implant Card, 52(4) Sampling of technical documentation and Article 61(6) (b) on mandatory Clinical Investigations

Definition outlined in in MDCG 2020-6 is being utilised as the criteria.



Outcome of consultation and technical assessments: approximately 50



Next steps:

- Adoption end of March/Early April



The measure, based on Article 36 (3) MDR / Article 32 (3) IVDR, proposes requirements on:

- Quotations;
- Timelines for conformity assessment activities, including clock-stops;
- Monitoring of timelines and costs;
- Re-certification.



Public feedback closed on 23/01.



Next steps:

- Comitology - exchange of views - 17/02
- Comitology - vote - TBC



HSA
Health Sciences Authority



IMDRF International Medical Device
Regulators Forum



Recent digital policy

Software Qualification & Classification

 [MDCG 2019-11 rev.1](#)



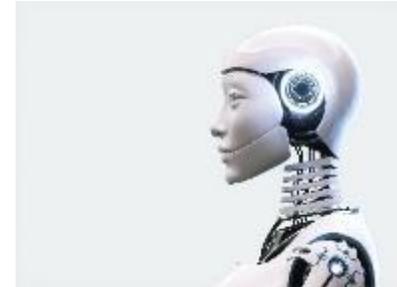
Wearable and sensor technologies

 [MDCG 2023-4](#)



Medical Device AI (MDAI)

 [MDCG 2025-6](#)



Online responsibilities for apps

 [MDCG 2025-4](#)



MDR / IVDR 2.0 (Commission proposal to revise MDR/IVDR)



Evaluation of MDR/IVDR – Key findings

Strengthened EU framework for safe and performant medical devices, through stricter pre-/post-market requirements, improved oversight.

Improved safety, evidence quality, and transparency

Confirmed added value of replacing fragmented national rules with a single regulatory framework.

Structural inefficiencies: regulatory complexity, insufficient proportionality, implementation delays, inconsistent application.

Strongly increased **costs and admin burden**, longer certification **timelines**, reduced **predictability**.

Unavailability of devices, especially innovative/niche. Loss of **competitiveness**, esp. for SMEs.

Transition period extensions provided temporary relief, but **core issues remain**.

LESSON LEARNED:

STRIKING THE RIGHT REGULATORY BALANCE IS CRITICAL



Revision of the EU medical device regulations



Overall objective of the MDR / IVDR revision:

Simplify the rules to **reduce administrative burden**, increase **predictability**, **shorten processes**, **improve cost-efficiency and effectiveness**, while keeping the **high level of patient safety** and **ensuring the availability** of devices.



- Revision proposal (covering MDR/IVDR, their annexes)
- supported by two Staff Working Documents: targeted evaluation and cost-savings analysis

The revision will make the sector more competitive in the internal market and globally, supports innovation for better patient care & aligns with international best practices.



Specific objectives of the revision



DIGITAL

Commission proposal amending MDR/IVDR: 16 December 2025

- **Proportionate Software Classification:** Targeted clarifications to Annex VIII (incl. Rule 11) to better align software classification with **actual clinical risk**, avoiding automatic up-classification where patient impact is limited & aligning with IMDRF N12 read in conjunction with N81.
- **Interaction with the EU AI Act – Clarifying Roles, Avoiding Duplication:** Medical device legislation remains the **primary safety framework** for MDAI, with the AI Act applying in a **complementary and non-duplicative manner**. Essential principles will be integrated directly in MDR/IVDR.
- **Lifecycle Management via PCCPs:** Enables **predetermined change control plans** for software, AI, etc., allowing NB-accepted updates.
- **Regulatory Sandboxes for Innovation:** Introduces **national and EU regulatory sandboxes** to support supervised testing and principle/regulatory science testing.
- [...]



INTERNATIONAL COOPERATION

*Codifying
long-standing
practices*

Commission proposal amending MDR/IVDR: 16 December 2025

- The proposal introduces *new legal provisions* in both MDR and IVDR establishing a **specific framework for international regulatory cooperation, convergence, and reliance mechanisms** (MDR: new Article 108a; IVDR: new Article 108b). These provisions are intended to:
- **Promote global regulatory convergence** with international partners and forums such as:
 - **IMDRF (International Medical Device Regulators Forum)**
 - **MDSAP (Medical Device Single Audit Program)**
- Facilitate structured cooperation and the **mutual sharing of best practices and regulatory outcomes**.
- Anchor the EU's regulatory system in international cooperation as a **legitimate long-term policy priority**.
- These new international cooperation clauses are **not merely aspirational** — they aim to create a **legal basis in the EU's primary medical device law** for structured, ongoing partnerships on a global scale.



Looking ahead

- ❖ Public feedback until March/April 2026
- ❖ Co-decision process



IVDR transition periods

- High risk: **31 December 2027**
- Medium risk: 31 December 2028
- Low risk: 31 December 2029

MDR transition periods

- High risk: **31 December 2027**
- Medium risk: 31 December 2028
- Low risk: 31 December 2028



Thank You!

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