



Regulatory Updates

MDR/ IVDR 2.0

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Topics



Revision MDR/ IVDR (Proposal)

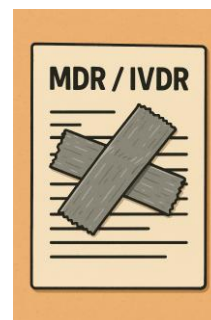


Disclaimer



PLEASE NOTE:

Text/ requirements will/ may change during
the process!



Strasbourg, 16.12.2025
COM(2025) 1023 final

2025/0404 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards simplifying and reducing the burden of the rules on medical devices and *in vitro* diagnostic medical devices, and amending Regulation (EU) 2022/123 as regards the support of the European Medicines Agency for the expert panels on medical devices and Regulation (EU) 2024/1689 as regards the list of Union harmonisation legislation referred to in its Annex I

MDR/ IVDR 2.0 Proposal

Published 16 December 2025

Specific objectives of the revision



EU COM rationale for the Revision proposal



Whereas 3 & 4

(3) In its targeted evaluation of Regulations (EU) 2017/745 and (EU) 2017/746, the Commission confirmed that the Regulations have strengthened the regulatory framework through **stricter requirements on the designation and oversight of notified bodies, the conduct of conformity assessments, and the generation of clinical evidence.** However, the evaluation also highlighted several shortcomings and inefficiencies in the regulatory framework, **resulting in unnecessary burdens for manufacturers.** Overly complex and often disproportionate requirements, costly, lengthy and unpredictable conformity assessment procedures affect the **availability of devices, the competitiveness of manufacturers** in the Union, **in particular of small and medium-sized enterprises, and innovation** in medical technology

(4) To address the shortcomings identified, the **existing rules should be simplified, and administrative burden should be reduced** **without jeopardising the high level of public health and patient safety.** Moreover, the **predictability and cost-efficiency** of the application of both Regulations should be enhanced to achieve their initial objectives.

Conformity Assessment (examples)



From "every 12 months" to "every 24 months in the absence of concerns from vigilance and PMS"

Reduction of annual surveillance on QMS



Only 'for cause' TD sampling for

- Class IIa, IIb and class III WET*
- Class C and Class B (except for self-testing)

Reduction of surveillance TD sampling



Class B: one device (was one device per generic device category)
MDR and IVDR class C initial sampling unchanged

Reduction of initial IVD Class B TD sampling



Only when justified based on concerns related to PMS or vigilance

Reduction of unannounced audits



Gap analysis from initial certification
Unclear how sampling will be done
"Predefined" periods for doing recertification

Recertification replaced by periodic reviews



No NB involvement if harmonized standards or CS applied

Ir devices



No NB involvement

Class A sterile IVD



NBs will have the possibility to replace on site audits by remote audits

Remote Audits



One TD per generic device group

Class III WET



Certification in general (examples)



Validity of certificates and recertification:

Removal of 5 years validity
Implementation of periodic reviews



Article 16 Repackaging and Relabelling

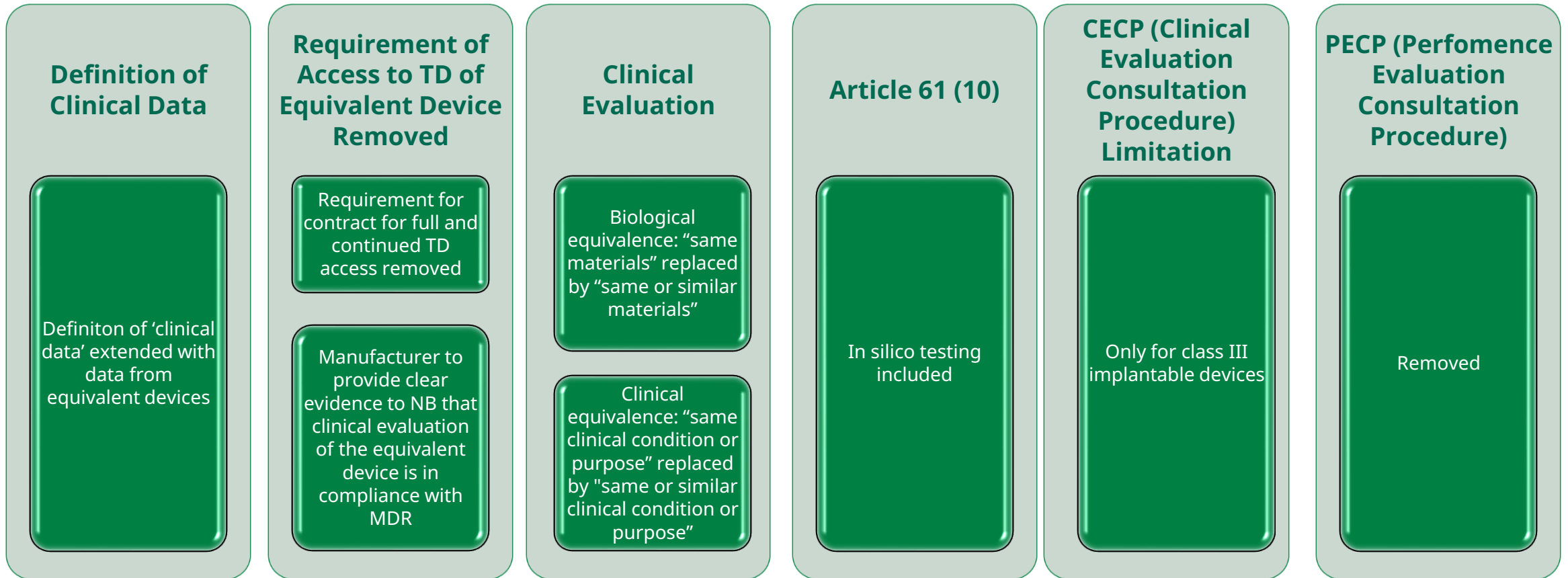
Requirements for NB certificate and notice obligation removed



Changes after certification

Distinguish between changes regarding the quality management system or the approved device
Distinguish between “without prior notification”, “without prior approval” or “only after approval”
Predetermined change control plan

Implications clinical (examples)



Well-Established Technologies (WET)



Definition of WET introduced

Deletion of current listing
Similar to MDCG 2020-6

WET incorporated into classification rules

E.g., 'are total or partial joint replacements, in which case they are classified as class III, with the exception of components such as screws, wedges, plates and instruments and other devices that are well-established technology devices

List of exempt devices removed

As definition included, list has been removed

PMS, Vigilance and Market Surveillance (examples)



PSUR frequency and scrutiny decreased

- Class IIb and class III/class C and class D
 - Updated in the first year after certificate is issued
 - Subsequently every two years
 - Or when significant change in benefit-risk determination or undesirable side-effects
- Class IIa - updated when necessary
- Class III or class IIb implantable, other than WET, the NB shall review during the surveillance assessment.
- Manufacturer and NB shall make such PSURs and evaluation available to CA through EUDAMED

NB involvement for serious incidents

- No 'standard' NB involvement in analysis of serious incidents and FSC actions
 - CA may request NB that issued the certificate for assistance
- NB tasked with
 - Assessment whether any reported serious incident or FSCA has impact on certificates to act on signals arising from vigilance data

Reporting timeline serious incident of 30d reinstated

- Instead of 15 - 30 days - reporting of a serious incident

New Cybersecurity reporting obligations

- Manufacturers must report within 30 days via EUDAMED:
 - Any actively exploited vulnerability in the device (as defined in Article 3(42) of Regulation (EU) 2024/2847; Cyber Resilience Act)
 - Any severe security incident (as referred to in Article 14(5) of the same Regulation)
- Reports must be sent simultaneously to:
 - The CSIRTs (Computer Security Incident Response Teams) designated as coordinators in the Member States where the device is available
 - The ENISA (European Union Agency for Cybersecurity)
- CSIRTs and ENISA will have access to EUDAMED

Classification (examples)



Down-classification of reusable surgical instruments

- Class I, regardless of location in body

Down-classification of MDSW

- Default classification as class I
- unclear conditions for higher classifications, e.g. critical/serious/non-serious "situation"

Down-classification of MDAI

- AI Act requirements no longer directly applicable (lex specialis rule)

Accessory to AIMD

- Classified in their own right

Annex XVI devices

- Covered under rule 9

Substances (rule 21)

- Include now substances which are to be placed on the human body

Classification dispute

- Process/ decisions streamlined
- Support by expert panel



Breakthrough



Background

Breakthrough Definition

Novelty & significant clinical impact

Orphan Definition

Incidence < 12k in EU, AND

Insufficient alternatives OR clinical benefit over alternative

Breakthrough/Orphan Status

Expert panel opinion

No formal designation

Commission empowered...

- To amend Art.52a via delegated acts
- To change conformity assessment procedure via implementing acts

Breakthrough guidance

- Limited impact for NBs
- Expectation NBs prioritise
- No option for early advice

Prioritisation of Conformity Assessment

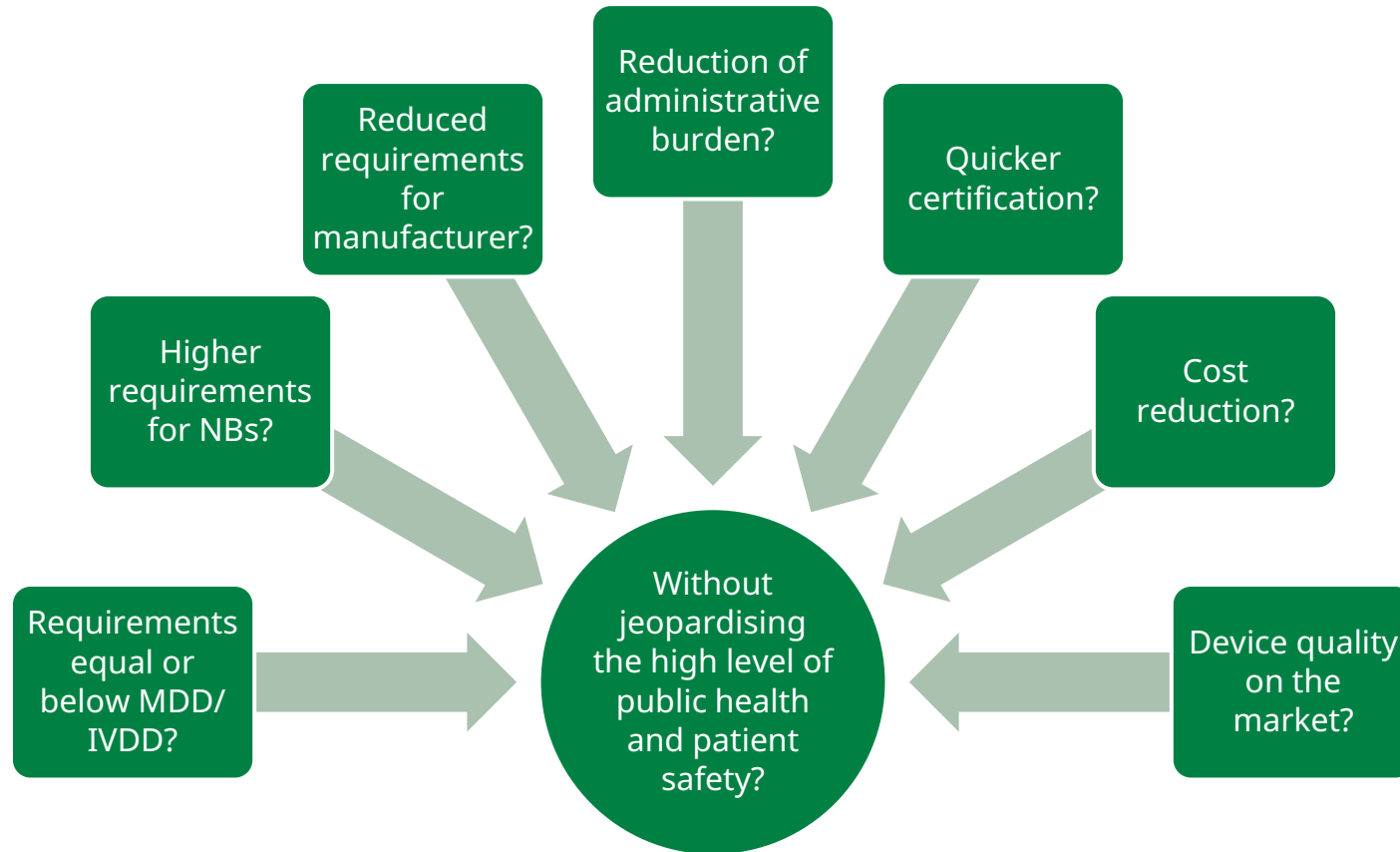
- NBs “shall prioritise”
- NBs may apply rolling review

Certification based on limited pre-market data

- Certificates under conditions
- Certificates with limited validity



MDR/ IVDR Revision



EU legislative process

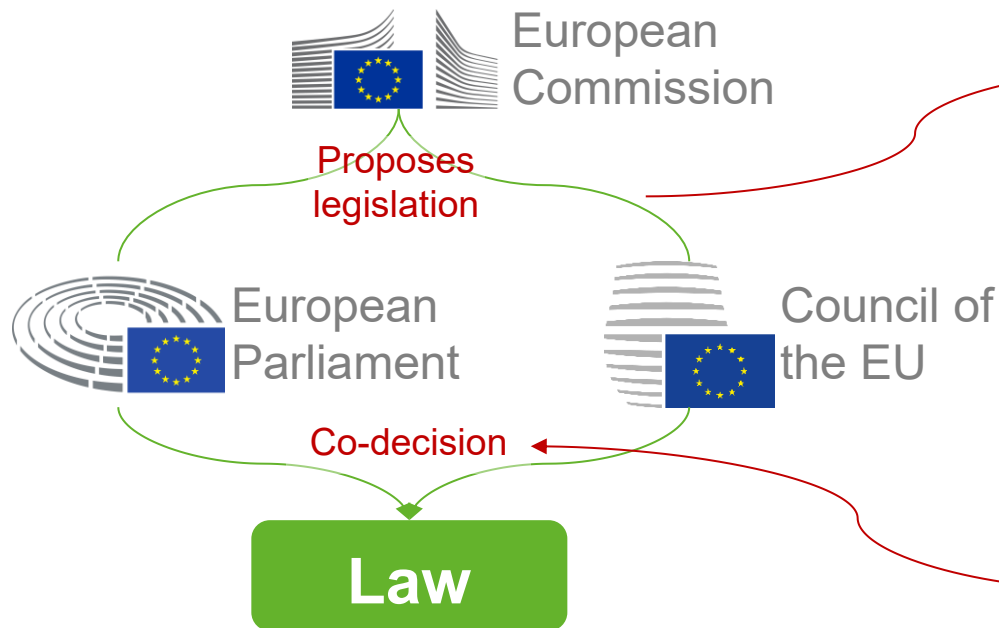
Co-decision



Ordinary Legislative Procedure

(=“co-decision”, Art. 294 TFEU)

- Up to three iterations of amendments ('readings') by Parliament and Council
- Process highly transparent



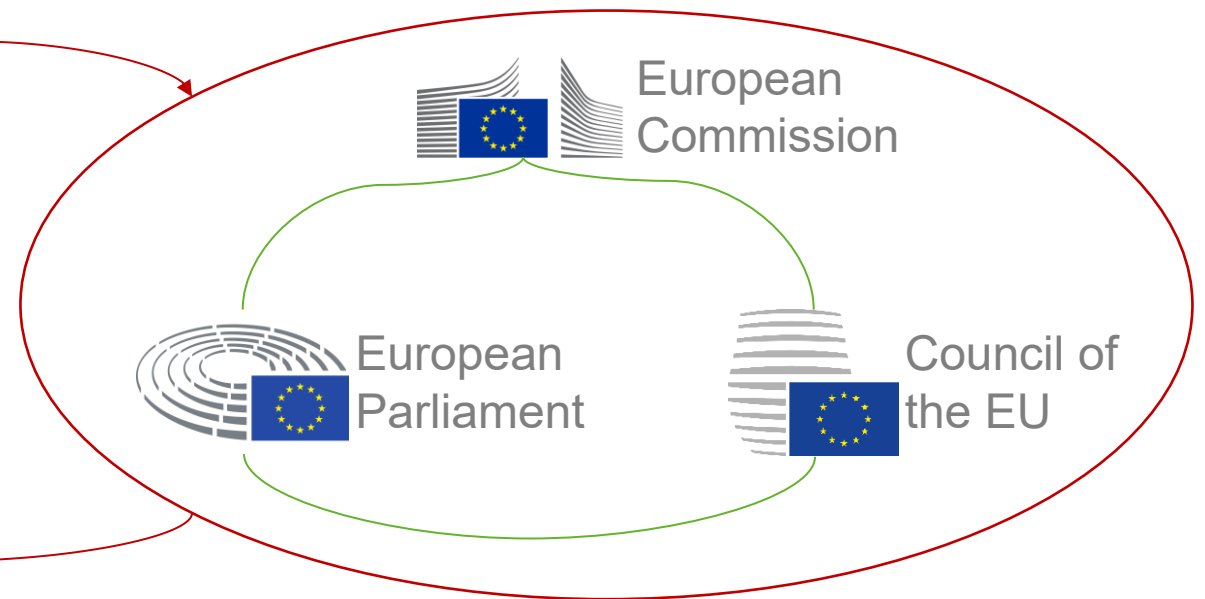
Trilogue

(not legally formalised)

Closed-door negotiations

Informal route to compromise in case of disagreement

Recently used for about 99% of new laws



Co-decision Procedure for MDR/IVDR Revision



Assumptions

NO	STEP NAME	DESCRIPTION	OUTCOME	DATE/ASSUMPTIONS
1	Commission Proposal	European Commission drafts and submits legislative proposal.	Proposal sent to Parliament and Council	16 Dec 2025
2	First Reading	Parliament and Council examine =“read” proposal; may amend, followed by Trilogue	If agreement in Trilogue→ Act adopted	Start : March 2026 Trilogue agreement: Q3 2028 (2,5 years)
3	Second Reading	If positions differ: Parliament reviews Council’s position; Council decides on amendments.	If agreement → Act adopted	
4	Conciliation	Joint committee drafts compromise text if still no agreement.	Compromise text prepared	
5	Third Reading	Parliament and Council vote on compromise text.	If both approve → Act adopted	
6	Publication & Entry into Force	Act published in Official Journal and becomes law.	Law enters into force	Q4 2028
7	Becoming Applicable	Act becomes applicable		02-2029 (range Q4 2028-Q4 2033)



Medical devices and in vitro diagnostics – targeted revision of EU rules

[Have your say - Public Consultations and Feedback](#) > [Published initiatives](#) > [Medical devices and in vitro diagnostics – targeted revision of EU rules](#)

In preparation

Call for evidence

Feedback period


08 September 2025 - 06
October 2025

Feedback: Closed

Commission adoption

Feedback period

07 January 2026 - 17 March
2026

Feedback: Open 

About this initiative

Summary

This initiative seeks to simplify EU rules for medical devices and in vitro diagnostics. It aims to ensure availability of safe and innovative devices to safeguard a high level of patient safety, public health and healthcare.

Drawing on an evaluation of the current rules, the initiative seeks to:

- make the EU medical device sector more competitive in the internal market and globally, to support innovation and reduce dependencies;
- make safety requirements more cost-efficient and proportionate.

Topic

Public health

Type of act

Proposal for a regulation

Call for evidence

Feedback: Closed

Feedback period

08 September 2025 - 06 October 2025 (midnight Brussels time)

[Medical devices and in vitro diagnostics – targeted revision of EU rules](#)

Questions?

