

2026-03-12

Skyddsnivå:

Sätt ett kryss
(X) framför rätt
skyddsnivå!

(K0) Ingen/låg
(K1) Grundläggande
(K2) Utökad
(K3) Hög

Ur Myndighetens perspektiv - Vad händer på EU-nivå?

Grupper inom EU-arbete medicinteknik

EU kommission

Committee on
Medical Devices

MDCG

MDCG CG

PMSV
Market Surveillance
Standards
CIE
New Technologies
IVD
Annex XVI
International Matters
NBO
Borderline &
Classification
Nomenclature
UDI
EUDAMED

CAMD

CAMD EG

HMA

Core Group
Medical
Devices

EMA

MDSSG
MD SPOC WP

EU kommission

Committee
on AI

AI Board

Notifying
authorities
AIA/(MDR,IVDR)

**EHDS
Board**

MDR/IVDR revision Commission proposal

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Unit “Medical devices”



European
Commission

#HealthUnion

Context



Challenges in implementation of MDR and IVDR: risk of shortages – several **extensions of transitional periods**

European Parliament resolution (October 2024), **EPSCO Council Conclusions** (June 2024) and **EPSCO debate** (December 2024)



European Commission's political guidelines 2024-2029: simplification, competitiveness, innovation, digitalisation, resilience



Commissioner Várhelyi's **mission letter**: availability and competitiveness of medical devices



Calls from **authorities, healthcare professionals, industry, patients and notified bodies** to address persistent implementation challenges and revise the Regulations



Targeted evaluation launched in 2024 – including many consultations of stakeholders and Member States. Findings: framework is strengthened, but many structural issues



Call for evidence (Sept/Oct 2025) for targeted MDR/IVDR revision



Commission proposal for MDR/IVDR revision 16 December 2025 + staff working documents on the evaluation and cost savings analysis (>€3 bn/yr)



Evaluation – 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 medical devices 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.

The revision will make the sector **more competitive**, in the internal market and globally, **by supporting innovation for better patient care.**

Specific objectives of the revision



Enhance
predictability
and
cost-efficiency
of certification

Conformity assessment procedures

- Pre- and post-submission ‘structured dialogue’ between manufacturer and NB based on documented procedures
- Possibility to replace on-site audits by remote audits
- Possibility to replace annual surveillance audits by audits every 2 years
- Unannounced audits – replace systematic once every 5 years by ‘for cause’
- Reduced fees for micro and small manufacturers; empowerment to set level and structure of NB fees
- Reduce NBs involvement for technical documentation for low/medium risk devices (class II MD, class B/C IVD)
- Remove NBs involvement for class A IVDs
- Remove maximum validity of certificates, keep periodic reviews

Special procedures

- Replace PECP for ‘new’ class D IVD by early scientific advice for class C/D IVD
- Limit scope of CECP to class III implants
- Reduce timelines for consultation of medicines and SoHO authorities (90+30d)
- Reduce scope of CDx consultation

Make
requirements
more
proportionate

Clinical evidence

- Adjust definition of ‘clinical data’
- Introduce definition of ‘well-established technology devices’ subject to lighter requirements
- Ease use of clinical data from ‘equivalent devices’
- Enhance possibility to demonstrate safety and performance based on non-clinical data (e.g. in silico)

Other

- Assessment of vigilance data – remove overlap between NCA and notified bodies
- Person Responsible for Regulatory Compliance – remove overly prescriptive qualification requirements
- Parallel distribution – remove QMS certification for relabelling/repackaging and prior notification
- Classification rules: adapt rules resulting in lower risk class (e.g. reusable surgical instruments; software)
- Language requirements: promote acceptance of another official language
- Co-packaged products: integrated and reduced labelling requirements

Reduce
administrative
burden
(reporting
obligations)

Reporting, assessment, approval of changes after certification

- distinguish between non-reportable, reportable and subject to approval
- introduce Predetermined Change Control Plan (PCCP)

Summary of Safety and (Clinical) Performance (SSCP, SSP)

- limit the scope, remove notified body validation and lay user version

Periodic Safety Update Reports (PSUR)

- reduce frequency for updating and remove separate notified body evaluation

Vigilance reporting

- increase timeline for reporting of serious incident not related to public health threat, death or serious deterioration of health from 15 to 30 days

Performance studies

- remove authorisation for studies involving routine blood draws
- remove notification for studies on CDx using left-over specimen

**Support
innovation.**
Address **special
situations**

Adapted conformity assessment procedures:

- breakthrough technologies and orphan devices

Regulatory sandboxes (national and EU level)

‘Single-use devices’: justification for single-use claim, facilitated reprocessing/reuse

Grandfathering for ‘legacy’ orphan devices

In-house devices: more flexible rules; extend the scope to IVDs made and used within laboratories for clinical trials of medicines

Shortage monitoring & crisis management

- Art. 10a - discontinuation/interruption of supply of certain devices: central IT tool for reporting (e.g. EUDAMED), list of devices subject to reporting, possibility for MSs to request information on supply chain vulnerability
- Derogations and special authorisations needed during PHE, crisis or disaster

**Streamline
procedures.**

**Improve
governance**

(1/2)

Coordinated oversight of notified bodies

- Streamline designation process and simplify extension of scope
- Fees from (candidate) notified bodies to cover participation of national experts in joint assessments
- Involvement of joint assessment teams for monitoring of NBs
- Dispute resolution mechanism between manufacturers and NB through national authorities
- Recognition that NBs act in the public interest

Coordination mechanism among NBs

- Strengthen the requirement for NBs and their staff to participate in coordination
- Bring the Notified Bodies Coordination Group under the MDCG

Regulatory status of a product and device classification

- Streamlined coordination among NCAs and involvement of expert panels

**Streamline
procedures.
Improve
governance
(2/2)**

Enhanced role for the EMA

Management of expert panels:

- Regulatory expertise to be included in panels (NB and competent authority experts)
- Recognition of the status of breakthrough and orphan devices
- Expanded early advice to manufacturers
- Greater use of expert panel advice to Commission and Member States for decision-making

Scientific, technical and administrative support for coordination among NCAs:

- Borderline and classification
- Clinical evaluation and investigation, performance evaluation and studies
- Vigilance and market surveillance
- Exceptional temporary authorisations (derogations)



Enable further digitalisation

- Extend possibility to provide e-IFUs (e.g. all IVDs for professional use)
- Allow digital labelling of information that is not critical for safe and effective use
- Enable digitalisation of conformity assessment procedures, documents and reporting (e.g. digital submissions, digital EU declaration of conformity)
- Reinforce requirements concerning online sales

**Align better with
other legislation
+ internally**

- **Enable single application process for authorisation of combined studies** (MDR/IVDR & CTR, Biotech Act)
- Alignment of vulnerability reporting with the Cyber Resilience Act
- **Single regulatory framework for AI medical devices**
- Remove (internal) inconsistencies: within MDR/IVDR, between articles and annexes

Promote
international
cooperation and
reliance

Strengthen Commission and Member States' participation in multilateral cooperation mechanisms:

- International Medical Device Regulators Forum (IMDRF)
- Medical Device Single Audit Program (MDSAP)

Introduce possibility for international reliance

- Empowerment to determine reliable jurisdictions' approvals (or parts thereof) or reliance mechanisms to be considered in the certification process

Looking ahead

- Translations in preparation
- Public feedback regarding proposal on Commission's [Have your say](#) website
- Ordinary legislative procedure ('co-decision')

Law

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](#)

Commission adoption

Feedback: Open

Feedback period

07 January 2026 - •••• 2026 (midnight Brussels time)



Feedback period extended

The eight-week feedback period is being extended every day until this adopted proposal is available in all EU languages.



The Commission would like to hear your views.

This adopted act is open for feedback for a period of **8 week(s)**. All feedback received will be summarised by the European Commission and presented to the European Parliament and Council with the aim of feeding into the legislative debate. Feedback received will be published on this site and therefore must adhere to the [feedback rules](#).



IVDR transition periods

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

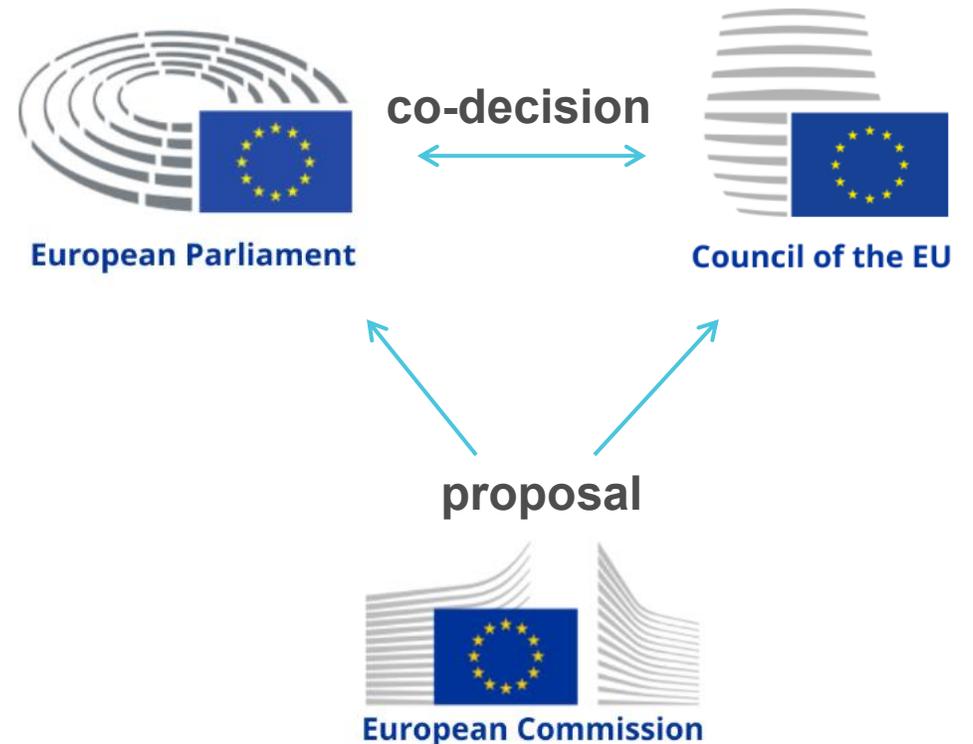
MDR transition periods

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



Co-decision process

- Examination of proposal by European Parliament and Council
- Negotiations between European Parliament and Council, with participation of European Commission
- Adoption by European Parliament and Council (co-legislators)



Short term measures

Pilot för
prövningar i
flera länder
pågår!

eIFU

Tillåten för
produkter som
endast är
avsedda för
professionell
användning

[EUR-Lex -
02021R2226-20250716](#)
[- EN - EUR-Lex](#)

Delegerade akter

WET

- Undantag från granskning av anmält organ för varje produkt
- Undantag från klinisk prövning
- Undantag från implantatkort

Genomförandeakt bilaga VII

- Offert
- Strukturerad dialog
- Tidslinjer och klockstop
- Recertifiering
- Monitorering

Breakthrough technologies

- Vägledning
- Pilot, EMA start Q2

EUDAMED

- Börja snarast!

- Du måste vara **färdig** med din aktöreregistrering, inklusive Läkemedelsverkets validering,

Aktörsregistrering i EUDAMED (2026-03-03)

- 557 tillverkare av CE-märkta produkter finns registrerade hos LV. En fjärdedel av dessa har inte registrerat i Eudamed.
- 47 auktoriserade representanter finns registrerade hos LV. En tredjedel av dessa har inte registrerat i Eudamed.
- 40 ansvariga för modulsammansatta produkter finns registrerade hos LV. Hälften av dessa har inte registrerat i Eudamed.

er, importörer och ansvariga för
senast 28 maj 2026.

Antal CE-märkta produkter som svenska tillverkare registrerat i Eudamed (2026-03-03):

- 15 624 (synliga produkter)
- 99 (ej synliga produkter vilka blir synliga först när anmält organ registrerat intyg)

Jämförelse: Enligt LVs nuvarande register släpper svenska tillverkare ut 95 755 produkter på marknaden

- Produkter som omfattas av "Master Files"

- Kontaktlinser:

Master UDI-DI ska tillämpas från 9 maj 2028

- Glasögonglas, glasögonbågar och läsglas

Master UDI-DI ska tillämpas från 1 nov 2028 – registrera senast 1 nov 2028.

- Specifika vägledningsdokument finns!

Nationell registrering

Registrering hos Läkemedelsverket

- Tillverkare av nationella medicinska informationssystem (NMI)
- Tillverkare av specialanpassade produkter
- Reprocessare som inte är vårdgivare
- Distributörer och importörer med ansvar för översättning/ommärkning och ompaketering enligt artikel 16.2–16.4 i MDR.



E-tjänst för faktureringsuppgifter

- Läkemedelsverket ska tillhandahålla faktureringsuppgifter. Aktörens ansvar att hålla dessa uppdaterade.

EUDAMED - Hjälp och länkar

- Läkemedelsverkets webb:
 - [Eudamed – europeisk databas för medicintekniska produkter | Läkemedelsverket \(lakemedelsverket.se\)](#)
 - [Registrering i Eudamed | Läkemedelsverket](#)
 - [Nyhetsbrev medicinteknik | Läkemedelsverket](#)
- EU-kommissionens samlingssida: [Medical Devices - EUDAMED \(europa.eu\)](#)
- EUDAMED Public: [EUDAMED database - EUDAMED \(europa.eu\)](#)
- EUDAMED Information Center: [EUDAMED Information Centre - PROD \(europa.eu\)](#)
- Inloggning till Eudamed PRODUCTION: [MDR-Eudamed - Welcome to EUDAMED](#)
- Inspelad workshop från EU-kommissionen: [EUDAMED Workshop – 21 May 2025 - Stuttgart, Germany - Public Health](#)
- Mejla frågor till oss på Registrator@lakemedelsverket.se
- Ring oss på 018 17 46 00 (telefontider enligt information på webbplatsen)

Proposal - Useful links

- [Proposal for a regulation to simplify rules on medical and in vitro diagnostic devices](#)
- Consolidated texts integrating the proposed changes (these documents have no legal effect)
 - MDR: [Articles](#) – [Annexes](#)
 - IVDR: [Articles](#) – [Annexes](#)
- [Q&A on simpler and more effective rules for medical devices](#)
- [Factsheet - Better rules for medical devices, better outcomes for EU patients](#)
- [Staff Working Document on targeted evaluation](#)
- [Staff Working Document on cost-savings analysis](#)