IMDRF International Medical Device Regulators Forum

EU Regulatory Update

International Medical Device Regulators Forum 28th Session
Sapporo, Japan – 16 September 2025

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DG Health and Food Safety

IMDRF International Medical Device Regulators Forum

Priorities

Continue	Implementation of the MDR/IVDR
Accelerate	Short-term actions: both legislative and non-legislative
Finalise	Targeted evaluation and revision (planned for Q4 2025)

IMDRF International Medical Device Regulators Forum

Implementation of MDR/IVDR

- Coherent and pragmatic application of **extended transitional provisions** for different types of devices to prevent potential shortages of existing and new/innovative devices
- Availability and capacity of notified bodies (currently 50 for the MDR and 18 for the IVDR in the NANDO information system
- Availability of harmonised standards (currently 32 for the MDR and 17 for the IVDR in the OJEU – including ISO 13485 (QMS), IEC 60601 series, ISO 14971 (RMS) *(more publications under preparation)*
- Adoption and enforcement of implementing and delegated acts for different aspects of the Regulations (most-recently: Master-UDI delegated act, Electronic instructions for use, orphan expert panel…), short-term measures
- MDCG guidance documents (updates and new)
- Development of EUDAMED ongoing




Short-term actions

Legislative and non-legislative

e-IFUs for medical devices (Reg. 2021/2226)

- Amended by Commission **Implementing Regulation (EU) 2025/1234** on 16 July 2025
- **Scope of the amendment:** broadly expanded to
  - ✓ allowing possibility to issue e-IFUs for most **medical devices intended for professional users**,
  - ✓ Inclusion of **devices without an intended medical purpose** listed in Annex XVI of Regulation (EU) 2017/745,
- **Streamlined the conformity assessment process** by removing the separate requirement for Notified Body review, eliminating redundancy with other assessment activities.
  - ✓ Including **link to e-IFUs in** the UDI module of **EUDAMED**.

Note: dual-use medical devices (both professional and lay-user): the IFU intended for the lay person must be provided in paper form.

Designation of a **paediatrics and rare disease expert panel**

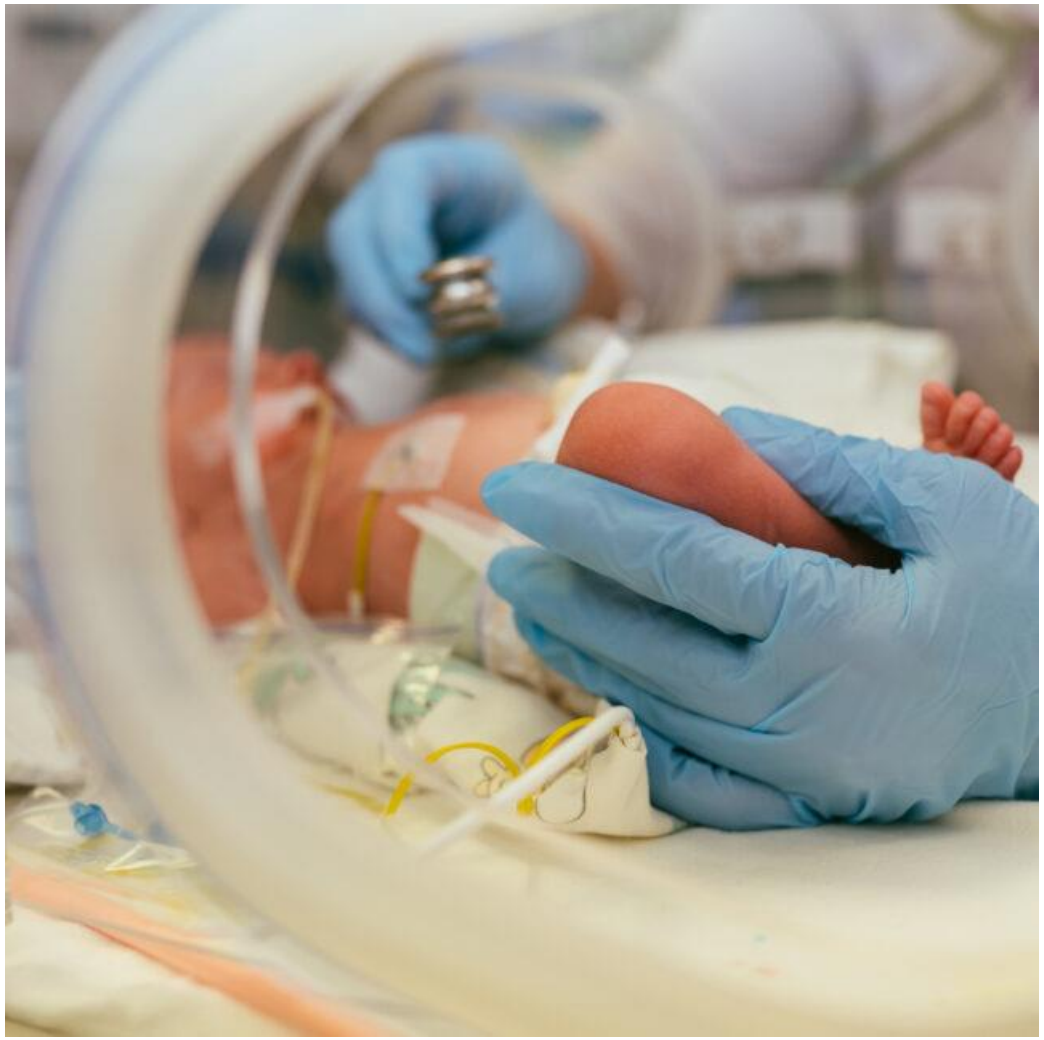


Image credit: Adobe images

- Amended by Commission **Implementing Decision (EU) 2025/1324** on 7 July 2025
- **Scope of the amendment:**
  - ✓ Designation of a new expert panel dedicated to **paediatrics and rare diseases**,
  - ✓ Updated administrative rules: work of sub-groups and procedures for designating rapporteurs,
  - ✓ Clarification of the role of the European Medicines Agency (EMA), now fully responsible for the panels' secretariat.
- **Aim:** to foster innovation and accessibility by offering expertise on the safety and performance of devices for rare diseases and children.
- **Expected output:** The new panel will enhance the regulatory process by providing opinions to support manufacturers and notified bodies under the EU Medical Device Regulation.

Short-term actions underway

Short-term actions – Legislative

☑ 1 Implementing regulation for **e-IFUs** for medical devices

- Public feedback closed
- Planned adoption date: **Q2 2025**

☑ 2 Establishment of an **Expert Panel on orphan and paediatric** devices

- Planned adoption date: **Q2 2025**

3 **Reclassification** of well-established technologies **(WET)**

- Request for evidence: processing input
- Planned adoption date: **Q4 2025**

4 Expansion of the **list** of well-established technologies **(WET)**

- Request for evidence: processing input
- Planned adoption date: **Q4 2025**

5 Implementing rules regarding **requirements to be met by Notified Bodies**

- Identified high priorities and ongoing discussion on input received
- Workshop with stakeholders (20 Feb 2025)
- Planned adoption date: **Q4 2025**

Short-term actions – Non-legislative

1. Guidance on **breakthrough technologies (BtX)**
2. Guidance on **orphan IVDs**
3. Guidance on **sampling of technical documentation**
4. Guidance on **certificates under conditions**
5. Guidance on **structured dialogue**
6. **IMDRF Guidance of high priority:** Pre-Determined Change Control Plans, Good Machine Learning Practices, Quality Management Systems, IVD Clinical Evidence and the Reliance Playbook
7. **MDSAP mapping activities** (NBCG-Med and MDCG)
8. **Support to other activities :** e.g. Horizon scanning, orphan devices, JAMS 2.0

EUDAMED

European Database for Medical Devices

Gradual roll out and timelines

Draft planning of the next steps

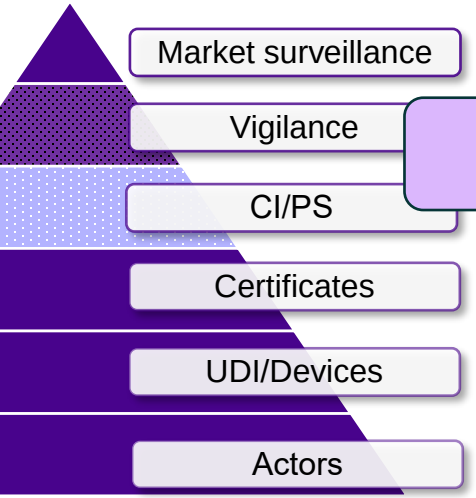
EUDAMED
European Database on Medical Devices

2025			2026				2027
Q2 2025	Q3 2025	Q4 2025	Q1 2026	Q2 2026	Q3 2026	Q4 2026	Q1 2027

Finalization of MVP Audit on 4 Modules

NonMVP Mandatory Use Development for 4 Modules

Mandatory use of Actor, UDI/Devices, NBs & Certificates, MSU



MVP Audit Vigilance

NonMVP Mandatory Use Development Vigilance

Mandatory use of Vigilance module

Publication of the notice of functionality in OJEU (Actor, UDI/Device, NB&CRF, MSU)

Register now!

EUDAMED
European Database on Medical Devices

Gradual roll out and timelines

Registration obligations timelines

Actor registration:

Now: voluntary use

6 Months after publication of the notice in the OJEU: mandatory use

Device registration:

Now: voluntary use

6 Months after publication of the notice in the OJEU: mandatory use of the module

Certificate

Now: voluntary use

6 Months after publication of the notice in the OJEU: mandatory use of the module

Market

No voluntary use

6 Months after publication of the notice in the OJEU: mandatory use of the module

Three hybrid workshops organised by COM

21 May 2025 ☑

Stuttgart (DE)

08 October 2025

Rome (IT)

03 December 2025

Brussels (BE)

https://tinyurl.com/4k864h5c

What to expect:

- Hands-on guidance on MDR/IVDR requirements related to EUDAMED
- Live navigation through the first four modules
- Practical aspects in data management and legal compliance

Developments in the digital space

Recent digital guidance

Software Qualification & Classification

MDCG 2019-11 rev.1

- Medical purpose beyond diagnostic devices to include **digital therapeutics**, new examples including **Class I**
- Clarifications on **modular approach** to placing on the market
- Interplay with European **Health Data Space**

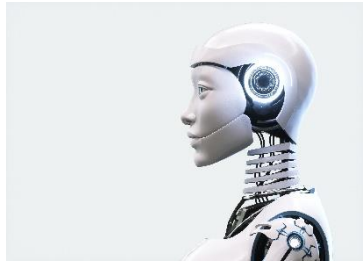
Wearable and sensor technologies

MDCG 2023-4

- Differentiation of different types of devices working in **combination** (system, combined, integral)
- Recognising that hardware may not be a medical device itself (**consumer product**)
- **Clinical and conformity** requirements for different ‘scenarios’

Medical Device AI (MDAI)

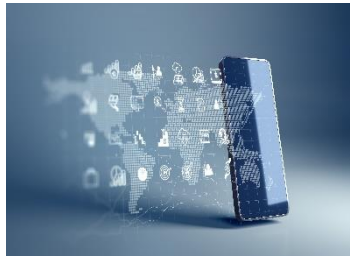
MDCG 2025-6



- Interplay with horizontal AI Act & clarification on **risk class applicability**
- Integrate **AI Act requirements** into existing MDR and IVDR pathways
- QMS, Risk-Management, Data Governance, Pre-determined Change Control

App store and manufacturer online responsibilities

MDCG 2025-4



- Host vs distributor/importer **roles**
- **Transparency** towards users: clear intended purpose, CE mark, UDI & documentation
- Mechanisms for **reporting & traceability**

Horizon Scanning System - MDs & IVDs

HADEA/2024/OP/0024

Objectives

Put in place a **horizon scanning system** in the area of **MDs and IVDs** in order to maintain an up-to-date overview of **new & emerging technologies**.

Aim:

Screen available sources for novel & emerging technologies
Assess features that may impact medical devices & IVDs
Identify opportunities, risks & trends related to these technologies

This horizon scanning was identified as a need in the context of implementing **MDR/IVDR legislation** to support **competitiveness & innovation** in the EU market, while ensuring a **high level of protection of health** for patients and users.

Contract value: €896 400
Contractor: TECHNOPOLIS FRANCE
Period: 30 months (contract signed on 06/06/2025)
Status: Ongoing

Read the contract award notice for more details.

Call for Evidence – EU cardiovascular health plan ♡ 📋

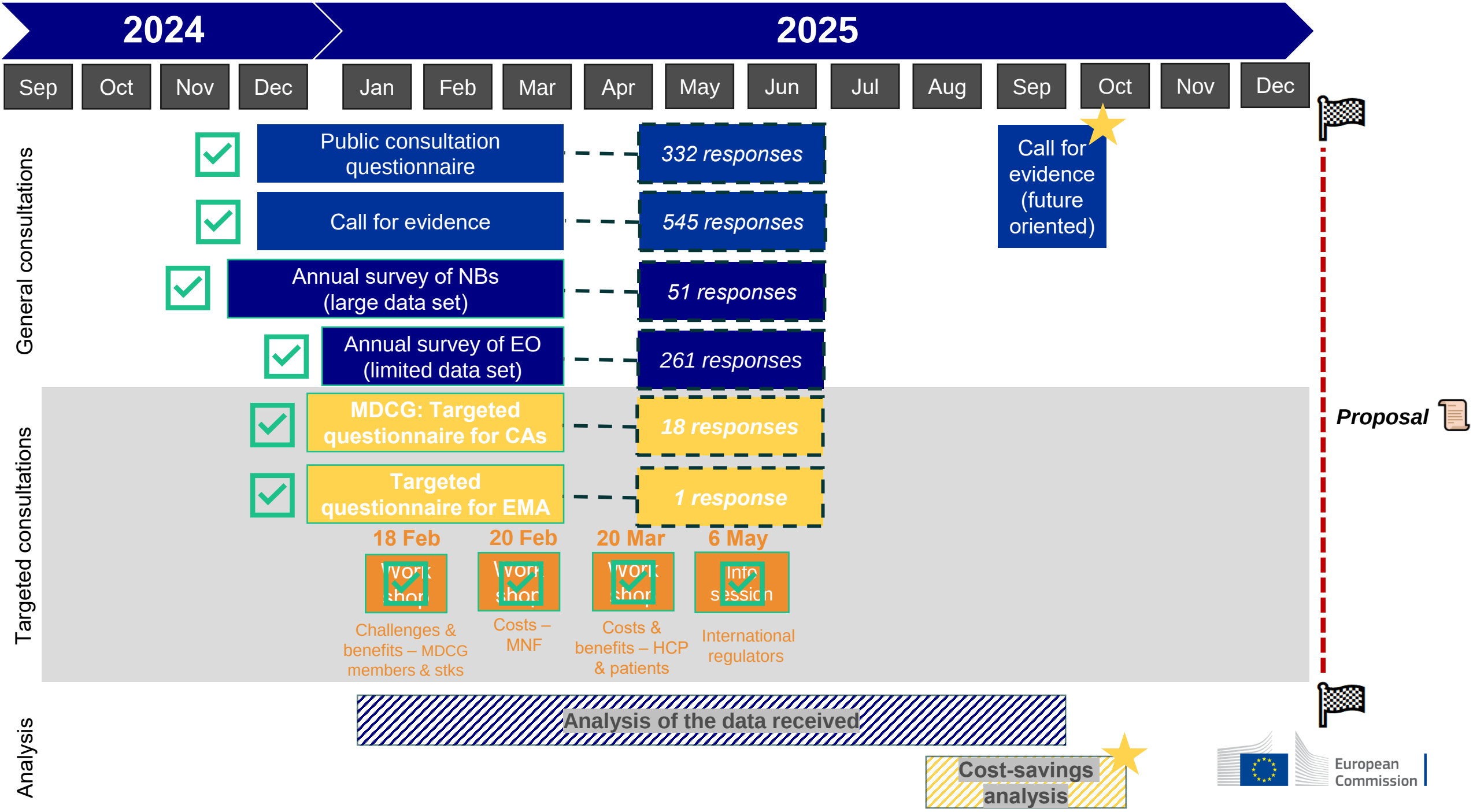
The plan will address:

- Prevention
- Early detection & screening
- Treatment & rehabilitation

Next to using the opportunities offered by **new technologies** (💻📱🤖 including digital & AI), **innovation** 💡 and **personalised tools** 🧬, the plan will also address the current **research & innovation gap** in **cardiovascular health** ♡.

📣 **Stakeholders are invited to submit feedback by 15 September** 📅. For more info, see: HEALTH AND FOOD SAFETY - EU Cardiovascular Health Plan: Call for Evidence

Targeted evaluation and follow-up


2024
2025
Sep
Oct
Nov
Dec
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
General consultations
Public consultation questionnaire
332 responses
Call for evidence
545 responses
Call for evidence (future oriented)
Annual survey of NBs (large data set)
51 responses
Annual survey of EO (limited data set)
261 responses
Targeted consultations
MDCG: Targeted questionnaire for CAs
18 responses
Targeted questionnaire for EMA
1 response
18 Feb
20 Feb
20 Mar
6 May
Challenges & benefits – MDCG members & stks
Costs – MNF
Costs & benefits – HCP & patients
International regulators
Proposal
Analysis
Analysis of the data received
Cost-savings analysis
European Commission

Feedback: Open

Call for evidence: Future oriented

*The initiative aims to **simplify** and **streamline** the regulatory framework, make it more **cost-efficient** and **proportionate**, while **preserving a high level of public health and patient safety** and the overall structure of the current regulatory framework.*

- **reduce** administrative burden including **reporting** obligations,
- **enhance** the **predictability** and **cost-efficiency** of notified bodies certification processes,
- make the conformity assessment **requirements more proportionate**, especially for low and medium risk devices and those that cater to special patient needs,
- enable further **digitalisation**,
- **streamline** procedures including governance,
- enable the EU medical device sector to benefit from **international cooperation** including reliance, where appropriate
- better **align** with **other** relevant **legislation**.

8 September - 6 October 2025

https://tinyurl.com/3tzhnm4u

Thank you

For further information regarding EU medical device regulations and developments: Medical Devices - New regulations - European Commission

For specific questions: sante-med-dev@ec.europa.eu