European Commission

Health

Better rules for medical devices, better outcomes for EU patients

December 2025

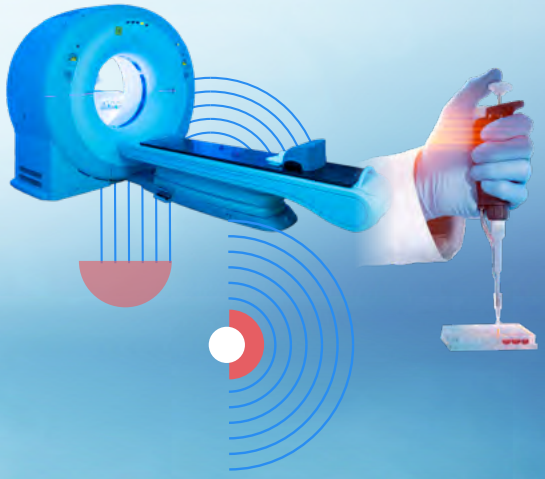
The medical devices sector is the second largest market in the world. Today's revision promotes competitiveness and innovation, setting one of the highest standards for medical device regulation globally.

- CONTACT LENSES
- SURGICAL MASKS
- BLOOD SCREENING TESTS
- BRAIN IMPLANTS
- PACEMAKERS
- LARGE MRI EQUIPMENT

One single clear framework for the AI-enabled Medical devices.
Over 38 000 medical technology companies in Europe.

Second largest market globally and a major employer in Europe with 930 000 people employed

The European medical technology market is estimated at around €170 billion in 2024.



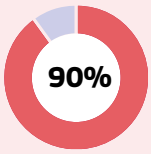
THE REVISION AIMS TO ENSURE:

- A high level of **patient safety and care**
- The **availability** of safe and innovative devices
- A more **competitive** EU medical device sector
- Support for **innovation**
- Faster **market access**

KEY ACTIONS OF THE REFORM

Reduce administrative burden, enhance coordination, simplify rules and streamline procedures and reporting obligations for all actors. Procedures for Medical Device AI will be streamlined to avoid duplications and facilitating single procedures.

Small and Medium sized Enterprises (SMEs) represent around

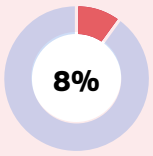


of medical device manufacturers in Europe.

More proportionate and targeted requirements which will make conformity assessments more balanced, especially for low and medium risk class devices and those for small patient populations.

Orphan devices are crucial for treating relatively small groups of patients, for example **children**.

Support for innovation and the development of breakthrough technologies through adapted conformity assessment procedures.



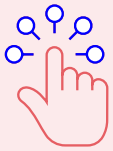
The average global R&D investment rate is estimated to be around **8%** in the **medical technology sector.**

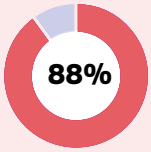
In **2024**, more than **15,700 patent application** were filed with the European Patent Office in the field of medical technology

Enhance legal certainty, predictability and cost efficiency of certification by reducing timelines, adjusting classification rules and the use of real-world evidence.

Across the EU, the use of **alternative methods** to collect clinical evidence, including real-world data, is estimated to generate around **200 million in savings per year**.

Increase digitalisation, for example by extending the possibility to provide electronic instructions for use and digital conformity assessment procedures.





of healthcare professionals prefer the use of **electronic instructions** for use compared to the paper version.

Improved coordination at EU level and streamlined procedures through more coordinated oversight of notified bodies and the provision of EU-level scientific expertise with a stronger involvement of expert panels and the European Medicines Agency.

WHAT ARE NOTIFIED BODIES?

Organisations designated by EU Member States to assess a device's compliance with EU legislation before it is placed on the market and can be used safely by healthcare professionals and patients.

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