European Commission

European Health Union:
Helping the transition to the new rules on medical devices and *in vitro* diagnostics

In 2017, the EU introduced new rules for medical devices and *in vitro* diagnostics **to ensure a better protection of public health and patient safety**.

Despite considerable progress in transitioning to these rules and the additional time given to the sector to implement them, the **transition remains slow**. In 2023, the Commission took measures to ensure the availability of medical devices and is now proposing taking additional steps to ensure the availability of high risk *in vitro* diagnostics by May 2025.

The priority is to ensure that patients have access to safe and qualitative medical devices and *in vitro* diagnostics.

NOTIFIED BODIES are organisations designated by EU Member States to assess, independently from the manufacturer, **a device's compliance** with **EU legislation** before it is placed on the market and **used safely by doctors and patients**.

SMALL AND MEDIUM SIZED ENTERPRISES (SMES) REPRESENT AROUND

95% OF MEDICAL DEVICE MANUFACTURERS IN EUROPE.

TIMELINE

2017
Adoption of Regulations on medical devices and *in vitro* diagnostics (Regulation 2017/745; Regulation 2017/746)

2020
Application of Regulation on medical devices postponed by 1 year due to COVID-19 crisis (Regulation 2020/561)

2022
Introduction of staggered transition periods in IVDR and longer transition for 'in-house' devices* (Regulation 2022/112)

2023
Introduction of staggered transition periods in MDR and removal of 'sell-off' date in MDR/IVDR (Regulation 2023/607)

2024
LEGISLATIVE PROPOSAL

- **Further extension of the transition period** for in vitro diagnostic medical devices to December 2027 for high risk devices, and December 2028 and December 2029 for medium and lower risk devices respectively
- **Earlier mandatory use** of some modules of the **European database** on medical devices
- New obligation for manufacturers to give **prior notice in case of disruption of supply** of certain medical devices and *in vitro* diagnostics

** 'in-house devices' are devices manufactured and used only within health institutions established in the EU*

ONGOING NON-LEGISLATIVE ACTIONS TO SUPPORT THE TRANSITION

ACTIONS TO INCREASE THE CAPACITY OF NOTIFIED BODIES AND HELPING PREPARE MANUFACTURERS

Position paper by Medical Device Coordination Group identifying actions to increase notified body capacity, the access to notified bodies and manufacturer preparedness (MDCG 2022-14 position paper)

Increasing the number of notified bodies

Consortium (NoBoCap) developing actions to increase the capacity of notified bodies and the preparedness of manufacturers (trainings) and facilitating access to notified bodies, **especially for SMEs** (matchmaking platform) (EU4Health)

Supporting coordination between **notified bodies** (EU4Health)

Tailored solutions for **orphan devices**

Targeted support to SMEs through Enterprise Europe Network

NEW: Development of further supporting tools such as **translation of nomenclatures**

SUPPORT FOR INNOVATION AND ADDRESSING SPECIAL NEEDS

Pilot on **scientific advice by expert panels for clinical development strategies** for high-risk devices

Orphan device support programme, focussed on paediatrics (EU4Health)

NEW: Additional pilots with **expert panels to support conformity assessment**

STOCK TAKING OF REGULATORY FRAMEWORK AND TRANSITION (EU4HEALTH)

Study on **governance and innovation**

Study to **monitor availability of medical devices on EU market**

NEW: Studies supporting the targeted evaluation of MDR/IVDR

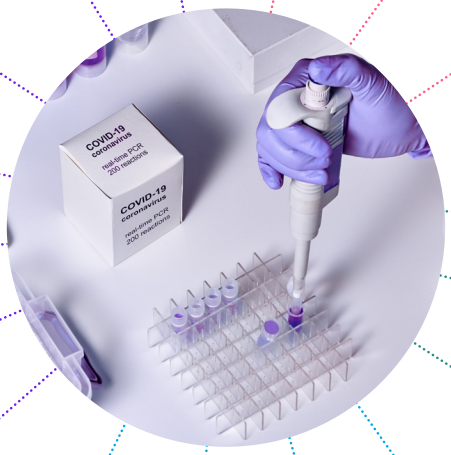
SUPPORT TO REGULATORY INFRASTRUCTURE AND PROCESSES (EU4HEALTH)

Support for **European database on medical devices**

Support for **designated EU reference laboratories** (*in vitro* diagnostics)

Joint Action on **market surveillance**

NEW: **Horizon scanning** for medical devices (EU4Health)



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