There are more than 500,000 types of medical devices on the market, ranging from low-risk products such as thermometers to high-risk devices such as pacemakers. The 2017 medical devices Regulation and the Regulation on in vitro diagnostics, establish a modernised and more robust EU legislative framework to ensure better protection of public health and patient safety.

Despite considerable progress with the implementation, the transition to the new rules has been slower than anticipated. Today, healthcare systems throughout the EU are facing a risk of shortages of life-saving medical devices for patients. Additional efforts are needed to address:

- Limited capacities of notified bodies
- Insufficient preparedness by market operators

The Commission is supporting the transition to enhance:

- Market readiness
- Coordination among authorities and notified bodies
- Efficiency of procedures and reduction of administrative burden

### Short term actions to mitigate risk of shortages of life-saving devices and disruption of supply

Legislative proposal:
- Staggered and conditional extension of the transition period until 2027/2028, according to risk class of the device
- Extended validity of certificates
- Cancellation of "sell-off" date i.e., allowing devices placed on the market before or during the transition period to continue to be made available without time limitation

Bridging measures based on application of market surveillance provisions

Gaining momentum to increase number of notified bodies

Implementation of actions to enhance notified body capacity and ensure availability of medical devices and in vitro diagnostics, as agreed by the Medical Device Coordination Group

---

1. MDCG 2022-18 position paper
2. MDCG 2022-14 position paper
Measures for a successful transition in the longer term

- Pilot project on scientific advice for clinical development strategies for high-risk devices
- Targeted support for SMEs through the Enterprise Europe Network
- Tailored solutions for orphan devices

Orphan devices are crucial for treating relatively small group of patients, especially children.

Small and Medium sized Enterprises (SMEs) represent around 95% of medical device manufacturers in Europe.

Financial support through the EU4Health Programme

- Survey on implementation progress
- Grant for capacity-building of notified bodies, facilitated access of SMEs to notified bodies and increased preparedness of manufacturers
- Joint Action on market surveillance
- Orphan devices support programme, focussed on paediatrics
- Support for stronger coordination of the Notified Bodies Coordination Group
- Study on innovation and governance

#HealthUnion