European Commission - Press release

Public health: Stronger rules on medical devices

Brussels, 26 May 2021

As of today, new EU rules on medical devices (MDR) enter into application, establishing a modern and more robust regulatory framework to protect public health and patient safety. The new rules start applying after a one-year postponement due to the unprecedented challenges of the coronavirus pandemic, addressing the need for an increased availability of vitally important medical devices across the EU.

The Regulation covers medical devices ranging from hip replacements to sticking plasters. It increases transparency and brings EU legislation in line with technological advances and progress in medical science. It improves clinical safety and creates fair market access for manufacturers.

Stella **Kyriakides**, Commissioner for Health and Food Safety, said: *"This is an important step forward for the protection of patients across Europe. The new rules improve the safety and quality of medical devices while providing more transparency for patients and less administrative burden for businesses. The legislation will strengthen innovation and our international competitiveness, ensuring that we are ready for any new and emerging challenges."*

In summary, the Medical Devices Regulation:

- **Improves the quality, safety and reliability of medical devices: it** imposes tighter controls on high-risk devices such as implants and requires the consultation of a pool of EU level experts before placing medical devices on the market. Clinical evaluations, investigations and the notified bodies that approve the certification of medical devices will be subject to tighter controls.
- **Strengthens transparency and information for patients,** so that vital information is easy to find. The European database of medical devices (EUDAMED), will contain information about each medical device on the market, including economic operators and certificates issued by notified bodies. Each device will have a unique device identifier so that it can be found in EUDAMED. More detailed labelling and electronic manuals will increase user-friendliness. Implant patients will receive an implant card with all the essential information.
- **Enhances vigilance and market surveillance:**Once devices are available on the market, manufacturers have to collect data about the devices' performance. EU countries will closely coordinate their vigilance and market surveillance.

Background

There are over 500,000 types of medical devices on the EU market. Examples of medical devices are contact lenses, x-ray machines, ventilators, pacemakers, software, breast implants, hip replacements and sticking plasters.

Medical devices have a fundamental role in saving lives by providing innovative healthcare solutions for the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.

The Regulation on medical devices is complemented by the Regulation on in vitro diagnostic medical devices (2017/746/EU) with a date of application of 26 May 2022. In vitro diagnostic medical devices are used to perform tests on samples, include HIV blood tests, pregnancy tests, COVID-19 tests and blood sugar monitoring systems for diabetics.

For More Information

Questions and Answers

Medical Devices Regulation

Overview | Public Health (europa.eu)

IP/21/2617

Press contacts:

Stefan DE KEERSMAECKER (+32 2 298 46 80)
Stephan MEDER (+32 2 291 39 17)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email