

**HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS**

New rules on medical devices

Regulation (EU) 2017/745 of 5 April came into force on 26 May to create a single set of rules applicable to all medical devices, other than in vitro diagnostic medical devices.

Here are some of the main changes to the rules that now come into force:

1. Broadening of the scope of application of the rules and of the concept of medical device

With this Regulation, medical devices without a medical purpose that have characteristics similar to medical devices (e.g., coloured contact lenses for cosmetic purposes), those which incorporate non-viable tissue or cell derivatives of human origin and predictive genetic tests are now covered by the rules on medical devices.

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2. The figure of the “authorised representative” established in the European Union

The figure of the “responsible person established in the European Union”, applicable to cases where a medical device manufactured outside the European Union is placed on the market, is replaced by the “authorised representative”. This authorised representative is responsible for ensuring the conformity of devices placed on the European Union market and acts as a contact person established in the Union.

The authorised representative is jointly and severally liable with the manufacturer for any defective devices.

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3. Single-use devices

The Regulation introduces the concept of “single-use device” and this category of device is intended to be used on one person during a single procedure (e.g., surgery).

Reprocessing and re-use of single-use devices may only take place insofar as permitted by national law and in accordance with the requirements set out in the Regulation.

4. Implant card

Manufacturers of implantable medical devices will now have to ensure not only that medical devices are supplied with the relevant information, but also that such devices are accompanied by an “implant card”.

The implant card must contain information that makes it possible to identify the device, including the name, serial number, lot number, the UDI, the device model, and the name, address and website of the manufacturer.

5. Establishment of a Unique Device Identification system

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A Unique Device Identification (UDI) system will be put in place that makes it possible to identify and facilitate the traceability of all devices placed on the market, except custom-made and investigational devices.

The system works by assigning a unique identification number to each medical device to allow it to be traced throughout the whole supply chain up to the end user.

This system is also accompanied by a database at the European level which ensures the traceability of medical devices marketed throughout the European area.

6. Establishment of a single European registration for economic operators

Economic operators – manufacturers, authorised representatives and importers – will now be identified with a single registration number, valid throughout the European Union. This will allow faster and simpler identification of these operators for the purpose of compliance with the requirements imposed by the Regulation.

7. Creation of a European database on medical devices: EUDAMED (“European Database on Medical Devices”)

The Regulation creates an EU-wide database for medical devices. This consists of a number of electronic systems to collate and process information regarding devices on the market and on the relevant economic operators, certain aspects of conformity assessment, notified bodies, certificates, clinical investigations, vigilance and market surveillance.

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The information in the EUDAMED database will be publicly accessible and a "Summary of safety and clinical performance characteristics" on high-risk medical devices will also be made available in this database.

8. Post-market surveillance system

The post-market surveillance phase will play an important role in the manufacturers' activity and, for each medical device, manufacturers must have a risk- and device-based post-market surveillance system. This must be part of the manufacturer's quality management system and it must collect, record and analyse data on the quality, performance and safety of the device during its entire lifetime. It must also produce reports at the discretion of the competent authority.

9. Electronic system for post-market surveillance and monitoring

The Regulation creates an electronic system on the electronic system for vigilance and post-market surveillance. The aim of this system, among others, is to collect information relating to serious incident reports and field safety corrective actions, trend reports and exchange of information between competent authorities.

Although the Regulation is directly applicable in the legal system of the Member States, several issues still require additional national regulation, particularly with regard to the system of penalties.

The implementation of the Regulation also depends on the preparation and publication of ancillary legislation (mandatory implementing acts and common specifications) and other methodological guidelines to enable the harmonised application of some of the rules imposed by the Regulation in all Member States. ■