By Eurofins Consumer Product Testing

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Medical Devices

EUROPE

New European Medical Device Regulation

New rules for the medical devices manufacturers.

The new Medical Device Regulation (MDR), Regulation (EU) 2017/745 April 2017 and published on the Official Journal of the European Union May 2017, entered into force on May 26th 2017 repealing Medical De Council Directive 93/42/EEC.

The MDR modifies the whole regulatory framework for Medical Devices market in Europe with change on severa topics, hereafter listed:

- Extension of Scope
- Medical Devices classification rules according to risk, contact duration and invasiveness
- Requirements for the Technical File
- Requirements for the Clinical evaluation
- Rigorous post-market
- CE marking procedures (annex and topics) and requirement and content of EU Declaration of Conformity
- Requirements for production and release of the product
- Identification of "qualified person"
- Implementation of unique device identification (UDI)
- Notified body: more detail for the notification
- Responsibility and role of manufacturers, importers, distributors and agents.

Manufacturers of currently approved medical devices will have a transition period of three years until May 2020 to meet the requirements of the MDR.

Click here for getting the Official Journal of the European Union and contact our experts for further information.