THE NEW European Union Medical Device Regulation (MDR)

The EU's Medical Device Regulation (MDR) was officially published on 5 May 2017 and came into force on 25 May 2017. The MDR will replace the EU's current Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC). Find out more about the key changes of the new MDR.

About the European Union (EU)

The EU population numbers more than **500 million**

The total medical device sales in the EU equals **€100 billion***

The EU medical device industry employs nearly **600,000***

The EU medical device sector is comprised of 25,000 separate companies, of which **95%** are small and medium sized enterprises*

What is the MDR?

The EU Medical Device Regulation (MDR) will replace the EU's current Medical Device Directive (93/42/EEC) and the EU's Directive on active implantable medical devices (90/385/EEC). The regulation applies to all Medical Device manufacturers who intend to place their medical devices on the European market.

Timeline of the MDR

- **2008** – EU Commission launches public consultation
- **2012** – EU Commission publishes proposal for MDR
- **2014** – EU Parliament reviews draft and proposes changes
- **2015** – EU Council reviews draft and proposes additional changes
- **2017** – MDR came into force on 25 May 2017
- **2020** – New devices and devices without a valid MDD/AIMDD certificate will have to meet MDR requirements from 26 May 2020
- **2024** – Extended transition period ends on 26 May 2024 for devices with valid MDD/AIMDD certification

Key changes

- Product scope expansion
- Implementation of unique device identification
- Rigorous post-market oversight
- Identification of person responsible for regulatory compliance
- Common specifications
- Reclassification of devices according to risk, contact duration and invasiveness
- More rigorous clinical evidence for class III and implantable medical devices
- Systematic clinical evaluation of Class IIa and Class IIb medical devices
- No "grandfathering" provisions

* http://ec.europa.eu/growth/sectors/medical-devices/index_en.htm

Get ready for the new Medical Device Regulation now

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