

The New Medical Device Regulation (MDR)

What is the MDR?

The Medical Device Regulation (MDR) is a new regulation that will replace the existing Medical Device Directive (MDD) 93/42/EEC and Active Implantable Medical Devices (AIMD) Directive 90/385/EEC. It applies to all medical device manufacturers who intend to place their products in the European Union (EU).

Key changes in MDR



Wider scope of regulated medical devices



More stringent clinical evidence and documentation



Increased focus on identification and traceability



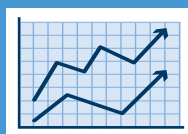
Definition of common specifications



Unannounced factory audits



Increased Notified Body authority and/or involvement



More rigorous vigilance and market surveillance



At least one person responsible for regulatory compliance

Timeline

Poly Implant Prothèse (PIP) scandal sparks global health scare



EU Parliament reviews draft and proposes changes

Expected publication of MDR



2012

2014

2015

Q4 2016

2017

▶ 2019

EU Commission publishes proposal for MDR, seeking to strengthen existing MDD




EU Council reviews draft and proposes additional changes

Notified Bodies can request re-designation and manufacturers can place devices on the market under new MDR

Expected end of three-year transition period

Global medical devices market

\$407
BILLION



Size of global medical devices market in 2020

R&D expenditure for medtech globally to grow 3.5% annually by 2020



The EU accounts for one-third of the global medical device market



Sources: www.evaluategroup.com/public/reports/EvaluateMedTech-World-Preview-2015.aspx www.medtecheurope.org/

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