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

- **2012** – Poly Implant Prothèse (PIP) scandal sparks global health scare
- **2014** – EU Parliament reviews draft and proposes changes
- **2015** – EU Council reviews draft and proposes additional changes
- **Q4 2016** – Expected publication of MDR
- **2017** – Notified Bodies can request re-designation and manufacturers can place devices on the market under new MDR
- **2019** – Expected end of three-year transition period

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

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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