**MDR – THE NEW EU MEDICAL DEVICE REGULATION**

**DIRECTIVE 93/42/EEC** – Medical Devices

**DIRECTIVE 90/385/EEC** – Active Implantable Medical Devices

**Medical Devices Regulation MDR**

**THE MOST IMPORTANT CHANGES**

- **Extended area of application (includes non-medical devices)**
- **UDI: Unique product number for every medical device**
- **More stringent requirements for technical documentation (TD)**
- **More stringent requirements for responsible persons: Expert knowledge of medical devices**
- **New scrutiny procedure for high risk medical devices**
- **Notified bodies more strictly regulated: New bodies to be chosen and inspected**
- **EUDAMED: Europe-wide database for more transparency and cooperation**

**TRANSITIONAL PROVISIONS**

- **4-year transition period:** Certification possible in line with old or new legislation (MDR)
- **No scope extension and substantial changes of MDD/AIMDD certificates**

- **COMES INTO EFFECT**
  - Published in the Official Journal
  - Legal acts relating to areas of competence for nomination of nominated body

- **APPLICATION DATE OF MDR**
  - Nomination of Notified Bodies strongly depending on activities of national authorities and EU Commission

- **MDD/AIMDD CERTIFICATES BECOME VOID**
  - MDD/AIMDD certificates as per Annex IV/4 become invalid

May 5, 2017

May 25, 2017

Nov 25, 2017

May 26, 2021

May 27, 2022

May 27, 2024

TUVRheinland

Precisely Right.