**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**
- **EUDAMED: Europe-wide database for more transparency and cooperation**

**TRANSITIONAL PROVISIONS**

- **3-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:**
  - May 5, 2017: Published in the Official Journal
  - May 25, 2017: Legal acts relating to areas of competence for nomination of nominated body
- **Application date of MDR:**
  - May 26, 2020: Nomination of Notified Bodies strongly depending on activities of national authorities and EU Commission
- **MDD/AIMDD certificates become void:**
  - May 27, 2024: MDD/AIMDD certificates as per Annex IV/4 become invalid
  - May 27, 2022: No scope extension and substantial changes of MDD/AIMDD certificates