

CE Marking



MDR Requirements

- Medical Device Regulation 2017/745
- Technical documentation
- Conformity assessment



Risk Classification

- Class I, IIa, IIb, III
- Rule-based classification
- Notified Body involvement



Clinical Evaluation

- Clinical data requirements
- Benefit-risk analysis
- Clinical evaluation report



Post-market Surveillance

- PMS plan & reports
- Vigilance reporting
- PSUR requirements



UKCA Divergence

- Post-Brexit UK requirements • Separate conformity assessment

