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

- UK Approved Body vs. Notified Body • Dual marking considerations