Elexes
www.elexes.com

EU MDR Device Classification Checklist

1. **Step-by-Step Classification Flow:**
   - Device type
   - Duration of contact
   - Degree of invasiveness
   - Anatomy involved
   - User population
   - User environment
   - Interoperability associated with medical and non-medical devices
2. **Rule Summary Table (Rules 1–22):**
   - Rule no., description, typical devices, applicable class
3. **Software Classification (Rule 11) Guide**
4. **Accessory vs Device –** What to Consider
5. **Documentation List:**
   - Classification rationale
   - Annex VIII mapping
   - Justification references
6. **Bonus:**
   - Pre-classification checklist before contacting NB
   - Reference links to MDR and MDCG guidance