

Invasive Medical Device Classification & Compliance Checklist

1. Device Definition & Intended Use

- Confirm the device meets the MDR definition of invasive per Annex VIII definitions. (penetration via body orifice/surface).
 - Identify duration of contact
 - Identify anatomical site and tissue contact type.
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2. Classification per EU MDR Rules (5–8)

- Rule 5: Body orifice devices (transient/short/long term).
 - Rule 6 & 7: Surgically invasive devices (transient & short-term).
 - Rule 8: Implantable/long-term surgically invasive devices.
 - Assign correct class (I, IIa, IIb, III) based on risk and duration.
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3. Notified Body & Conformity Assessment (EU specific)

- Determine if Notified Body involvement is required (usually for Class IIa+).
 - Identify applicable conformity assessment route (Annex IX, Annex X + XI)
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4. Technical Documentation & Risk Management

- Compile a complete technical file per MDR/region requirements.
 - Include ISO 14971-based risk management documentation.
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5. Clinical Evidence & Evaluation

- Collect clinical evidence proportional to risk class.
 - Prepare a Clinical Evaluation Report (CER) where required.
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6. Post-Market Surveillance (PMS) & Vigilance

- Establish PMS and PMCF processes (EU).
 - Implement adverse event reporting & Field Safety Corrective Action (FSCA) procedure for all regions.
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7. Labeling, UDI & Registration

- Ensure labeling, IFU and Unique Device Identification compliance.
 - Verify symbols per ISO 15223-1
 - Language requirements per target market
 - Register device in EUDAMED (EU), FDA database (US), or ARTG (Australia).
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8. Quality Management System (QMS)

- Apply ISO 13485 or equivalent QMS requirements as needed.