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Medical Device Labeling & IFU Submission Readiness Checklist

Labeling Essentials

- Device name clearly identified
- Manufacturer information included
- UDI, lot, or serial number present (if applicable)
- Required symbols and warnings included

Intended Use & Claims

- Intended use is clearly defined
- Claims are supported by evidence
- Claims do not exceed approved indications
- Consistent messaging across all documents

IFU Requirements

- Instructions are complete and easy to understand
- Warnings, precautions, and contraindications included
- Setup, use, and maintenance information provided
- Critical safety information is clearly visible

Regulatory Alignment

- FDA requirements assessed
- EU MDR Annex I requirements assessed
- Cross-document consistency verified
- Recent design or labeling changes reviewed