ISO 20417:2021 Compliance Checklist for Medical Device Labeling

- **Device Identification –** Include device name, model/catalog number, serial or lot number, and UDI.
- **Manufacturer & Economic Operators –** Provide manufacturer's name, address, and details of importer/distributor if applicable.
- **Symbols & Explanations –** Use ISO 15223-1 symbols consistently; add explanations if symbols are not universally understood.
- **Warnings & Precautions –** State intended purpose, contraindications, storage/handling conditions, and expiration/manufacture date.
- **Marking & Labeling –** Ensure device and packaging have durable, legible markings that remain visible throughout use.
- **Instructions for Use (IFU) –** Supply clear IFUs covering installation, operation, maintenance, troubleshooting, and disposal.
- **Electronic IFU (if applicable) –** Provide accessible, reliable, and secure e-IFUs with availability for at least two years post-market.
- **Language & Regional Adaptation –** Translate IFUs and labels into required languages per country-specific rules.
- **Risk & Usability Alignment –** Check that all information supports safety and effectiveness per ISO 14971 (risk) and IEC 62366 (usability).
- **Traceability Details –** Include lot/batch codes, manufacturing site (if required), and distributor/importer identifiers.
- **Regulatory Cross-Check –** Verify compliance against MDR, IVDR, FDA, and other regional regulations.
- **Document Control –** Maintain version control of labels, IFUs, and e-documents as part of QMS.