# EU MDR Readiness Checklist: 2025 Edition

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- **MDR Timelines –** transition periods, certificate validity, and key deadlines by device class
- **Device Classification –** confirm the right MDR risk class
- Clinical Evaluation – clinical data, literature review, and evidence prep
- **GSPR Summary –** simplified table with requirements
- Technical Docs – device description, design files, risk files, labeling
- **EUDAMED Steps –** actor registration, SRN, UDI assignment, device module registration
- **PRRC Requirements –** defined roles, qualifications and duties
- **Notified Body Prep –** conformity assessment route, key questions, audit readiness, common pitfalls
- **PMS Plans –** post-market surveillance planning, vigilance, and reporting
- **PSURs –** applicability by device class and required content
- **Labeling & IFU –** languages requirements, symbols, UDI, MDR updates
- **Economic Operators –** duties of authorized representatives, distributors/importers
- **PMCF –** when required and how to plan PMCF activities and reporting
- **Red Flags –** common gaps & mistakes that delay CE mark