MDD to MDR Transition Checklist

Gap Analysis
- Compare existing MDD documentation against MDR requirements to identify compliance gaps and areas needing updates.

Device Classification Review
- Re-evaluate device class under MDR rules to confirm correct classification and applicable conformity assessment routes.

Technical Documentation Update
- Revise your Technical File / Design Dossier to meet MDR content, structure, and documentation requirements.

Clinical Evaluation & Evidence
- Strengthen clinical evaluation reports, including PMCF planning and data analysis, ensuring alignment with MDR expectations, risk management, and state-of-the-art considerations.

Quality Management System Alignment
- Ensure your QMS aligns with MDR requirements, including procedures for post-market surveillance, vigilance, and risk management.

Labeling & UDI Implementation
- Update labels, IFUs, and implement UDI requirements, and ensure traceability of devices according to MDR formats and timelines.

Notified Body Engagement
- Confirm MDR designation status of your notified body and plan audits and submissions accordingly.

Post-Market Surveillance & Vigilance
- Establish proactive systems for PMS and vigilance systems, including trend reporting, and periodic safety update reports (PSURs), with defined responsibilities and timelines.

Supply Chain & Supplier Controls
- Communicate MDR expectations to suppliers and ensure their compliance impacts are addressed.

Training & Internal Readiness
- Train relevant teams on MDR changes, maintain training records, and ensure readiness for inspections and audits.