MDR Readiness Checklist (EU MDR 2025–2028)

Use this checklist to confirm MDR transition eligibility, packaging and sterilization readiness, and technical documentation com

A) Portfolio-Level Readiness

- [ ] MDR transition plan approved (scope, timelines, owners)
- [ ] Cross-functional team assigned (QA/RA, Packaging, Sterilization, Ops, Regulatory)
- [ ] Budget and notified body (NB) slots reserved for 2025–2028
- [ ] QMS mapped to MDR + ISO 13485; consider FDA QMSR alignment
- [ ] SOPs updated for MDR Annex II/III technical documentation structure

Evidence / Link:

B) Device-Level Eligibility (Legacy Status)

- [ ] Valid MDD/AIMDD certificate on file (issued before May 26, 2021)
- [ ] EU risk class verified (III, IIb, IIa, I)
- [ ] No significant change to design or intended purpose since MDR applicability
- [ ] Ongoing compliance to MDD/AIMDD requirements (incl. PMS)
- [ ] Written agreement with an MDR-designated notified body
- [ ] Risk evaluation confirms no unacceptable risk

Evidence / Link:

C) Packaging Validation (ISO 11607)

- ☐ SBS design defined; material specifications current
- ☐ Compatibility with device, sterilization modality, and labeling confirmed
- ☐ Packaging process qualification complete (IQ/OQ/PQ)
- ☐ Seal integrity validation with acceptance criteria and repeatability
- ☐ In-process controls and routine monitoring implemented
- ☐ Distribution simulation testing (shock, vibration, compression, climatic)
- ☐ Aging studies support shelf life (accelerated and/or real-time)
- ☐ Visual inspection criteria and AQL documented
- ☐ Defined revalidation triggers (material/supplier/equipment/label-UDI)

Evidence / Link:

D) Sterilization Validation & Routine Control

- ☐ Modality defined (EtO / Radiation / Moist Heat / e-beam)
- ☐ Validation reports current (ISO 11135/11137/17665)
- ☐ Bioburden monitoring program; alert/action levels set
- ☐ SAL justified; dose/cycle established
- ☐ Routine control (BI/CI; parametric release where applicable)
- ☐ Requalification frequency defined; last RQ date documented
- ☐ Compatibility demonstrated between sterilization and SBS

Evidence / Link:

E) Distribution, Labeling & UDI/EUDAMED

- ☐ Transport profiles defined; worst-case conditions justified
- ☐ Post-distribution inspection and CAPA pathway defined
- ☐ UDI carrier validated for all packaging levels; data integrity verified
- ☐ Label changes assessed for SBS impact (dimensions/adhesives/print heat)
- ☐ Registration planning aligns with EUDAMED modules

Evidence / Link:

F) Significant Change Management (MDCG 2020-3)

- ☐ Formal change-evaluation template (decision tree, rationale, risk)
- ☐ Historical changes since MDR applicability reviewed
- ☐ Supplier/material/sterilization/packaging/tooling changes documented
- ☐ NB pre-consultation strategy for borderline cases

Evidence / Link:

G) Risk Management & Post-Market Inputs

- ☐ ISO 14971 risk analysis covers packaging & sterilization hazards/controls
- ☐ Residual risk and benefit–risk updated
- ☐ PMS/PSUR and vigilance outputs feed risk review & revalidation

Evidence / Link:

H) Technical Documentation (Annex II/III)

- ☐ Tech file follows MDR Annex II/III headings
- ☐ Traceability matrix maps requirements to evidence
- ☐ Packaging validation complete (design, validation, aging, distribution)
- ☐ Sterilization validation complete (cycle, SAL, bioburden, RQ)
- ☐ UDI/labeling evidence and impact evaluation included
- ☐ Document control in EDMS; versioning/sigs current

Evidence / Link:

I) Supplier & Site Controls

- ☐ Packaging material suppliers qualified; CoAs/specs on file
- ☐ Sterilization vendors qualified; quality agreements current
- ☐ Supplier change-notification clauses for materials/equipment/sites
- ☐ Recent supplier audits completed; findings closed

Evidence / Link:

J) Training & Readiness

- ☐ Training records current for packaging/sterilization procedures
- ☐ MDR Annex II/III awareness training completed
- ☐ Internal mock audit against MDR technical documentation

Evidence / Link:

K) Submission & Timeline Control

- ☐ Submission schedule synchronized with NB capacity
- ☐ Critical path includes revalidation lead times (aging, distribution, RQ)
- ☐ KPIs defined (files ready, gaps, NB queries, audit findings)

Evidence / Link:

L) Device-Level Summary (Complete per SKU)

- ☐ Device Name / Catalogue Number
- ☐ EU Risk Class
- ☐ Legacy Status (Y/N)
- ☐ NB Agreement Date
- ☐ Packaging Validation Status (IQ/OQ/PQ; last RQ)
- ☐ Sterilization Validation Status (modality; last RQ)
- ☐ Distribution Testing Status (method; date)
- ☐ Shelf-Life Justification (AA/RT; expiry)
- ☐ UDI/Labeling Status
- ☐ Open Gaps / Risks
- ☐ Target Submission Window

Evidence / Link:

Notes