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FREE RESOURCE · EU MDR COMPLIANCE

EU MDR 2017/745 *Regulatory Readiness* Checklist

Class I through Class IIb Non-Implantable Devices

25 documentation requirements across 7 compliance areas
Each item referenced to the specific EU MDR article or standard

Class I | Class IIa | Class IIb Active

EU MDR 2017/745 | MEDDEV 2.7/1 Rev 4 | ISO 13485:2016 | ISO 14971:2019 | EN ISO 15223 | MDCG Guidance

25	7	3	1
Checklist Items	Compliance Areas	Device Classes	Regulatory Framework

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HOW TO USE THIS CHECKLIST

Review each item against your current documentation. Tick items that are fully in place. Items left unticked represent gaps to address before notified body submission. Each item references the specific EU MDR article, annex, or standard that creates the requirement — verify directly against the source document. This checklist covers Class I, IIa, and IIb non-implantable devices. Scope badges on each item indicate which device classes the requirement applies to.

01 Quality Management System

☐	Quality manual current, approved and version-controlled	ISO 13485:2016 §4.2.2	All
☐	Documented CAPA procedure implemented and records maintained	ISO 13485:2016 §8.5.2	All
☐	Complaint handling procedure documented and operative	ISO 13485:2016 §8.2.2	All
☐	Management review completed within preceding 12 months	ISO 13485:2016 §5.6	All

02 Technical File Structure

☐	Device description, intended purpose and classification documented	EU MDR Annex II §1 Annex VIII	All
☐	GSPR compliance mapping completed against Annex I requirements	EU MDR Annex I Annex II §6.1	All
☐	Design and manufacturing information documented	EU MDR Annex II §3	All
☐	Reference to previous and similar device generations included	EU MDR Annex II §2	IIa / IIb

03 Labelling and IFU

☐	Device labels comply with EU MDR Annex I Section 23 requirements	EU MDR Annex I §23	All
☐	EN ISO 15223 symbols used with accompanying legend	EN ISO 15223-1:2021	All
☐	Instructions for Use (IFU) complete and language-appropriate for EU markets	EU MDR Annex I §23.4	All
☐	Labelling reviewed against EU MDR — MDD labelling is NOT sufficient	EU MDR Annex I §23 Art. 10(11)	All

04 Clinical Evidence

☐	Clinical Evaluation Plan (CEP) drafted per MEDDEV 2.7/1 Rev 4 §6	MEDDEV 2.7/1 Rev 4 §6 Annex XIV Part A	IIa / IIb
☐	Systematic literature search conducted and documented per CEP	MEDDEV 2.7/1 Rev 4 §7 Annex A4	IIa / IIb
☐	Clinical Evaluation Report (CER) drafted per Annex XIV Part A structure	EU MDR Annex XIV Part A MEDDEV 2.7/1 Rev 4 §10	IIa / IIb
☐	Equivalence justification adequate — access to predicate tech file confirmed	EU MDR Art. 61(4) MDCG 2020-5	IIa / IIb
☐	PMCF Plan documented per Annex XIV Part B	EU MDR Annex XIV Part B MDCG 2020-7	IIa / IIb
☐	Clinical summary sufficient for Class I self-declaration	EU MDR Art. 61(2) Annex XIII	Class I

05 Risk Management

☐	Risk management file established per ISO 14971:2019	ISO 14971:2019 EU MDR Annex I §8	All
☐	All hazards identified — including use-related and electrical hazards (active devices)	ISO 14971:2019 §5 IEC 60601-1 §13 (active)	All
☐	Residual risks evaluated and benefit-risk determination documented	ISO 14971:2019 §8 EU MDR Annex I §8	All

06 Post-Market Surveillance

☐	Standalone Post-Market Surveillance Plan (PMSP) document exists	EU MDR Art. 84 MDCG 2022-21	All
☐	Post-Market Surveillance Report (PMSR) process defined — Class I	EU MDR Art. 85	Class I
☐	Periodic Safety Update Report (PSUR) schedule defined — Class IIa+	EU MDR Art. 86 MDCG 2022-21	IIa / IIb
☐	Serious Adverse Event and Field Safety Corrective Action reporting process in place	EU MDR Art. 87–89	All

07 UDI, EUDAMED and Registration

☐	UDI assigned via accredited Issuing Entity (GS1, HIBCC, or ICCBBA)	EU MDR Art. 27 EUDAMED	All
☐	UDI carrier (DI + PI) present on device label and packaging	EU MDR Art. 26 Annex VI Part C	All
☐	EUDAMED actor registration complete — manufacturer and EU AR registered	EU MDR Art. 30–31	All
☐	EU Authorised Representative appointed and named on labelling (non-EU manufacturers)	EU MDR Art. 11 EUDAMED	Non-EU

What to Do With Your Results

All items ticked

Your documentation is in strong shape for notified body submission. Consider commissioning a VerityNodes Regulatory Readiness Audit to confirm the assessment and identify any gaps this checklist does not capture.

5–15 items unticked

You have significant gaps that will likely result in notified body non-conformities if not addressed. Prioritise Critical items (UDI, EUDAMED, CER, PMSP) first. A Regulatory Readiness Audit will map every gap to its specific article with a prioritised remediation roadmap.

More than 15 items unticked

Your documentation requires substantial work before notified body submission is viable. Attempting submission in this state risks a major non-conformity, significant delay, and additional notified body fees. Commission a Regulatory Readiness Audit first — it will define exactly what needs to be built and in what order.

Ready to know exactly where your documentation stands?

Commission a Regulatory Readiness Audit — gap report with specific article citations, severity ratings, and a prioritised remediation roadmap. From $1,500 one-time.

veritynodes.ai/audit →