EMERGO by UL

European MDR Readiness Checklist

Items / Questions	Status	Notes
1. Does your product fall under the definition of a medical device or accessory under the MDR? Does MDR change the classifications of your medical devices from the MDD? Is your device included in MDR Annex XVI as a product without an intended medical purpose?	Yes ☐ No ☐ Not Sure ☐	
2. If your device is Class I self-declared, does your Quality Management System (QMS) address all the elements in MDR Article 10?	Yes ☐ No ☐ Not Sure ☐	
3. If your device is upclassified from Class I self-certified and you are taking advantage of the 4-yr exemption to 2024 allowed under Corregendum 2, are you still planning to meet the remaining MDR compliance requirements (e.g. QMS, PRRC, EOs, liability, etc.)?	Yes ☐ No ☐ Not Sure ☐	
4. Are you leveraging MDD CE certificates for existing devices? Do you plan significant changes to your devices before the expiry of the certificates?	Yes ☐ No ☐ Not Sure ☐	
5. Have you performed a gap analysis and identified potential gaps between MDD and MDR? Do you have a quality plan for your transition (QMS and Technical documentation) from MDD to MDR?	Yes ☐ No ☐ Not Sure ☐	
6. Have you reviewed the compliance of your device to the relevant General Safety and Performance Requirements (GSPR) in MDR Annex I? Do you have test reports or other documented evidence of conformance to all applicable GSPR?	Yes ☐ No ☐ Not Sure ☐	
7. Does your CER reflect MEDDEV 2.7.1. rev 4 at a minimum? If your CER does not contain clinical data does it include a rationale? Do you have a clinical evaluation plan and post-market clinical follow-up (PMCF) plan in place reflecting MDR Annex XIV?	Yes ☐ No ☐ Not Sure ☐	
8. Have you revised your Technical Documentation to meet the requirements in Annex II?	Yes ☐ No ☐ Not Sure ☐	

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9. Have you revised your agreements with your Economic Operators (EOs : authorized representative, importers, distributors) to meet the requirements in Articles 11 – 14? Have you obtained sufficient liability coverage proportionate to you device(s) risk class?	Yes ☐ No ☐ Not Sure ☐	
10. Do you have a post-market surveillance plan in place reflecting MDR Annex III, and specifically establishing a proactive and systematic process to collect any PMS-related information?	Yes ☐ No ☐ Not Sure ☐	
11. Have you identified a person(s) that meet the qualification criteria for the Person Responsible for Regulatory Compliance (PRRC) per Article 15?	Yes ☐ No ☐ Not Sure ☐	
12. Have you confirmed that your Notified Body will be designated to MDR (including your device(s) codes(s)), or will you need to change your NB?	Yes ☐ No ☐ Not Sure ☐	
13. Do you have a written plan for meeting the MDR requirements by the dates established by Articles 120 “Transitional provisions” and Article 123 “Entry into force and date of application”?	Yes ☐ No ☐ Not Sure ☐	
14. Are your QA/RA/audit personnel trained to the MDR? Have you conducted an internal audit to verify compliance?	Yes ☐ No ☐ Not Sure ☐	

Assess how you did:

If you answered No or Not Sure to any of the questions above, your MDR compliance may be at risk.
Contact us for assistance on these and other MDR compliance questions.
We specialize in YOUR questions and have more than 25 years of experience in global medical device consulting.

* Note that the manufacturer is also an EO.