European IVDR Readiness Checklist

EMERGO by UL

Items/Questions	Status	Notes
1. Do you have a good understanding of In Vitro Diagnostics Regulation (IVDR) requirements and the impact of such requirements on your company?	Yes ☐ No ☐ Not Sure ☐	
2. Do you know your IVDR classification and the expiration dates of any Notified Body certificates?	Yes ☐ No ☐ Not Sure ☐	
3. Do you know your IVDR classification and which path to conformity assessment you expect to take?	Yes ☐ No ☐ Not Sure ☐	
4. Do you have a written strategy related to the organization of your devices into regulatory classes and groupings?	Yes ☐ No ☐ Not Sure ☐	
5. Do you have an accredited ISO 13485 quality management system (QMS)?	Yes ☐ No ☐ Not Sure ☐	
6. If you answered "No" to Question 5, have you performed a gap analysis of your current QMS against ISO 13485?	Yes ☐ No ☐ Not Sure ☐	
7. Do you have a clear understanding of the applicable IVDR General Safety and Performance Requirements (GSPRs) as well as any required supporting documentation?	Yes ☐ No ☐ Not Sure ☐	

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8. Do you have a good understanding of the analytical, clinical and/or other evidence required to compile a performance evaluation report?	Yes ☐ No ☐ Not Sure ☐	
9. Are your risk management files compliant with EN ISO 14971:2012 (or 2019)?	Yes ☐ No ☐ Not Sure ☐	
10. Do you have a post-market surveillance (PMS) plan according to IVDR Annex III?	Yes ☐ No ☐ Not Sure ☐	

Assess your responses

If you answered "No" or "Not Sure" to any of the questions above, Emergo by UL can help.
Contact us for assistance on these and other IVDR compliance questions.
We specialize in answering your questions and have more than 25 years of experience in global medical device consulting.