

# EU IVDR (2017/746) Progress Self Assessment

The deadline for EU IVDR is May 26, 2022. Use this readiness questionnaire to assess the current state of your progress. Good luck!

	Yes	No	Don't Know
<b>Project Management Structure</b> Do you have a proactive project management structure to oversee the completion of your EU IVDR tasks?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Product</b> Have you identified and reviewed all of the new and/or updated IVDR sections relative to the IVDD?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Process</b> Are you >75% complete with conducting a gap assessment of the regulation to identify processes (e.g., GSPRs, Technical Documentation) that must be created or updated?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Product</b> Have you conducted a financial viability assessment of pipeline and existing products to validate transition to the EU IVDR?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Product</b> Have you conducted the classification assessment of your product families to define how the EU IVDR will impact current processes for your products?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Product</b> Have you assessed the level of effort needed to address the updated classifications and routes of conformity for your IVDRs?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>People</b> Have you identified all of the roles, responsibilities, and owners to be created/updated due to EU IVDR?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>People</b> Have all impacted, internal stakeholders been identified and made aware of how they will be impacted by the EU IVDR and are they clear on the changes/updates in processes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Partners</b> Have you assessed all partners (e.g., suppliers, distributors, manufacturers) to ensure that they are also working to become compliant with EU IVDR?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Technology</b> Have your impacted technical systems been updated to support processes related to interim EUDAMED-related EU IVDR changes?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>Software</b> Have you identified and assessed all impacted software, apps, and supporting content for compliance with EU IVDR?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
<b>TOTAL SCORE</b>			

## How many "Yes" responses did you mark?

**< 4  
Uh-oh!**

We need to meet immediately to discuss strategy. This regulation will not be delayed!

**5 - 8  
Getting There!**

Let's chat to discuss how you can effectively close out this work.

**9 +  
Great Job!**

Keep up the good work and contact us if you need any help.

Schedule a call with our team to discuss your results!

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