Resources to support your transition

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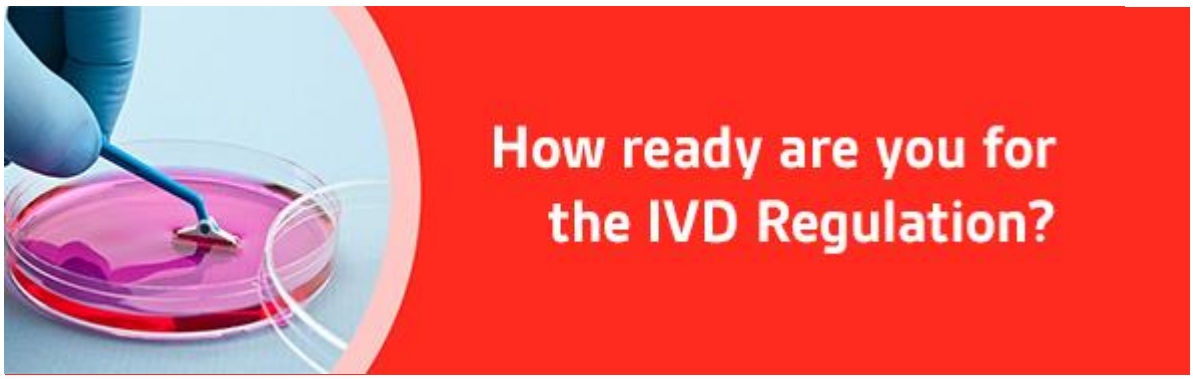
Contact us
+44 345 080 9000
eu.medicaldevices@bsigroup.com



We recently conducted in-depth interviews with 49 In-Vitro Diagnostic (IVD) Manufacturers to see how ready the IVD industry is for the IVD Regulation (IVDR) and we found out:

- 75% of respondents had no experience with a Notified Body as their products are currently self-declared
- Over 50% of respondents were not prepared to meet the requirements of the IVDR
- Many manufacturers need additional information on reclassification of devices, clinical evidence, post market surveillance and more.

The IVD industry is undergoing significant change and BSI is committed to ensuring a smooth transition for all clients wishing to certify to the IVDR.

We would be grateful if you could provide information around your plans for transitioning from the IVD Directive to the new IVD Regulation. We're aware of the significant change the transition will bring to our clients and would like to hear from you about your plans so that we can ensure our service will be ready to meet your requirements.

Please take a few minutes to complete our survey >>

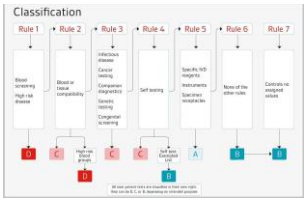
Here are some resources to support your transition...

IVDR Readiness Review

Our interactive Readiness Review can be used to complete a gap analysis of your current documentation and systems against the requirements of the IVDR. Detail how you intend to meet the new requirements, and list the documents and records that allow you to demonstrate conformity to the Regulation.

Download now

Classification Chart



Have you classified your device(s) yet? Use our handy Classification Chart to understand which classification devices should fall under.

View chart

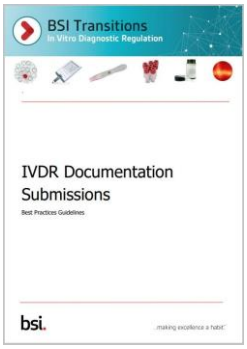
Join our webinar on IVDR Readiness

Wednesday 29 May 2019, 4pm BST

How ready are you for the IVD Regulation? Register to join our webinar where Erica Conway, BSI's Global Head – In Vitro Diagnostics, will discuss the IVDR Readiness Review which can facilitate your internal preparation and be used as a useful tool for planning your transition strategy.

Register now

IVDR best practice guide



Prior to placing a device on the market, manufacturers must undertake an assessment of the conformity of that device, in accordance with the applicable conformity assessment procedures. To minimize delays and reduce the time to certificate decision, we've produced the **IVDR Documentation Submissions – Best Practices Guidelines**.

Download now

Your BSI team is here to support you on your journey, so please talk to us about your plans early on in your preparation. Further information can be found on our **IVDR revision page**.

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