Your IVDR Transition Toolkit

The IVDR Date of Application is approaching

Are you ready for the May 2022 deadline?

The **In Vitro Diagnostic Regulation (IVDR) EU 2017/746** entered into force in May 2017 with a five-year transition period. Manufacturers have the duration of the transition period to update their Technical Documentation to meet the requirements and comply with the Regulation before the Date of Application of the IVDR in May 2022.

Conformity Assessments from a full scope IVDR Notified Body

BSI has two Notified Bodies, one in the UK (0086) and one in the Netherlands (2797), both of which have full scope designations to the IVDR and MDR.

Supported by a dedicated IVD team of 19 technical specialists, who have an average of 20 years' experience, BSI is able to provide conformity assessments for CE marking of IVD medical devices whatever the outcome of Brexit.

More information is available on our website: **www.bsigroup.com/ivdr**

Use our resources to support your transition.

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Inspiring trust for a more resilient world.

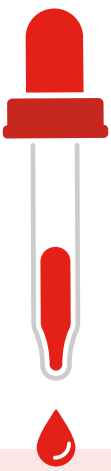
It is important that you start your application early

The transition to the IVDR requires you to plan and implement the new requirements, undergo a conformity assessment for your device, and make any necessary adjustments before May 2022.

It is important for you to have an understanding of the IVDR before applying for conformity assessment to CE mark your device and place it onto the EU market.

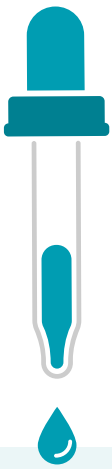
Use this toolkit to access the key resources you need to prepare for your transition.

Your IVDR Transition Toolkit



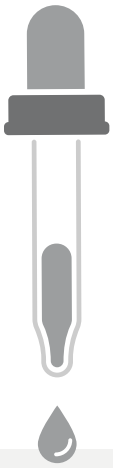
Brochures and guidance documents

- IVDR FAQs
- IVDR Readiness Review
- Conformity Assessment Routes Guide
- IVDR Training Courses
- IVDR Best Practices Guidelines



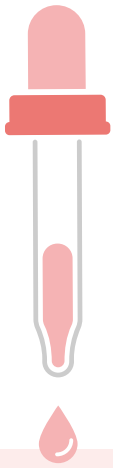
Whitepapers

- QMS for IVDs
- IVD classification issues
- Post-market surveillance
- Risk management



Webinars

- Conformity Assessment Routes
- IVDR application process
- GSPR and the IVDR
- QMS requirements under the IVDR



Training

- IVD to IVDR transition
- Requirements of the IVDR for CE marking
- Implementation of the IVDR for CE marking

For more information on these and our full range of IVDR training courses, visit our website: **bsigroup.com/en-ZA**

Talk to BSI today

Call: **+27(0)12 004 0279**

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