In Vitro Diagnostic Medical Devices

Justifiably proud of our status as a full scope IVD Medical Devices Notified Body

As a manufacturer of an In Vitro Diagnostic (IVD) medical device, you must ensure you meet the relevant requirements outlined in the In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746.

It is critical to work with a notified body that understands the industry and has the experience to review and confirm your product's readiness for market – efficiently, promptly and robustly. At BSI, our technical specialists have extensive experience and can support you through the process of certifying your IVD medical device.

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.

bsi.

...making excellence a habit.™

Defining IVD Medical Devices?

An IVD medical device is defined in the IVDR as:

"any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body..."

The definition then outlines the principle or sole purpose of these devices. In addition, an IVD medical device must have a medical application or purpose. For more clarity on the definition of IVD medical devices, please refer to the IVDR (EU) 2017/746.

"One of the most significant changes introduced by the IVDR is the level of oversight from the notified bodies and third parties. Many IVD medical devices currently on the market in Europe under the In Vitro Diagnostic Directive (IVDD) are self-certified and notified body involvement isn't required. This changes significantly under the IVDR with the majority (an estimated 90%) of IVD medical devices subject to notified body conformity assessment before being brought on to the EU market."

Dr Erica Conway

Global Head of IVD, BSI Medical Devices

Meet our experienced IVD team

Our IVD team has a broad range of industry and regulatory experience, including product design and development, manufacturing, testing and regulatory expertise, and is able to offer CE certification services for IVD medical devices under the IVDR.

Our IVD technical specialists are product experts in their respective fields. With an average of over 20 years' experience, they have undergone rigorous regulatory training.

From the experts

Have your IVD device portfolio well-organized (preferably around "what is a device" according to how you are going to assign Basic UDI-DI and UDI-DI) and understand your transition strategy. Requirements for Technical Documentation are defined in Annex II and Annex III of the IVDR – use this and our helpful IVDR Best Practices Guidelines to work on your Technical Documentation against the new requirements.

Examples of products we cover

- Blood glucose monitors
- Cancer diagnostics
- Clinical chemistry assays
- Companion diagnostics
- Devices for blood grouping
- Devices for the detection of infectious agents
- Devices for human genetic testing
- Devices for tissue typing
- Immunoassays
- PCR assays including next generation sequencing panels
- Self-tests and near-patient testing devices

Reasons to make BSI your IVD Notified Body

Experience and product expertise

The benefits of having experienced, professional and well-qualified technical specialists cannot be overstated in the complex and ever-changing medical device industry. BSI Medical Devices has a team of over 700; within that team are our technical experts with experience encompassing the full range of medical devices and management system standards.

BSI Group is a global network of over:

5,000 people supported by 12,000 industry experts in more than 193 countries

Focus on service

Clients work with us because we understand the challenges IVD medical device manufacturers face in bringing compliant products to market efficiently and safely. We offer a range of flexible product review services providing you with efficient pathways to bring your product to market.

Global market access

We are a global organization, trusted and recognized around the world. 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.

Confidence and robust reviews

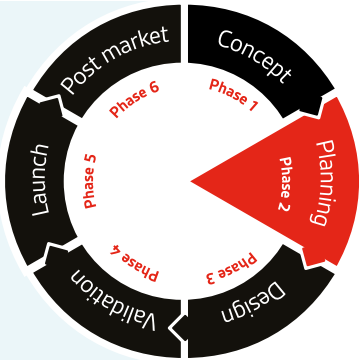
Our comprehensive review process combined with our world-leading experience as a Notified Body will ensure that your conformity assessment process is both efficient and robust.

Passion for patient safety

Our mission is to ensure patient safety while supporting timely access to global medical device technology. We strive to set the global standard in thorough, responsive, robust conformity assessments, evaluations and certifications.

The Product Lifecycle: when to consider clinical and regulatory requirements

An understanding of the complex clinical and regulatory requirements early in the product lifecycle could ensure you gain the competitive advantage needed to bring your product to market. Consolidated clinical and regulatory planning will assist you in maximizing resources and reducing the risk of costly redevelopments later in the lifecycle.
Visit our website for more information about the product lifecycle.



How can BSI support your IVD medical device launch?

Be prepared

In the competitive IVD medical device marketplace, ensuring that product development meets all regulatory requirements is essential. We provide guidance and training to support you through the application process.

Worldwide access

We offer a wide range of proven regulatory and quality management programs that work together for full international compliance. Our Quality Management System (QMS) solutions include ISO 13485, ISO 9001, ISO 14001 and many more.

We are a recognized Certification Body in Hong Kong, Japan, Malaysia, Singapore and Taiwan, and a recognized MDSAP Auditing Organization for all participating Regulatory Authorities.

Seamless transfer to BSI

We can offer a seamless service with comprehensive support and the absolute minimum level of disruption.

Certification support and additional services

We offer continual support throughout the certification process and beyond; we also offer:

- **access to more than 34,000 standards** and related products, as well as online guidance documents
- **expert training** delivered online or face-to-face, either in-house or through our public training courses
- **regulatory updates** and a newsletter service focusing on industry changes, helping you to plan for the future
- **webinars** delivered by our experts on complex regulatory issues
- **comprehensive whitepapers** providing the latest insights on key industry topics

Navigating your transition to the IVDR

The In Vitro Diagnostic Regulation (IVDR) (EU) 2017/746, which replaces the EU In Vitro Diagnostics Directive (IVDD) 98/79/EC, entered into force on the 25 May 2017 marking the start of a five-year transition period for manufacturers and economic operators. Manufacturers wishing to apply to a notified body for a conformity assessment of their IVD medical device, including those that are currently self-declaring conformity under the IVDD, have until the Date of Application of the IVDR in May 2022 to update their Technical Documentation to meet the requirements and comply with the new Regulation.

The IVDR brings with it significant changes to the regulatory requirements for IVD medical device manufacturers and introduces a new rule-based classification system with stricter notified body oversight, as well as significant changes to the depth and requirements of the associated Technical Documentation. It also brings changes to the relationship between manufacturers and economic operators.

Our IVDR Best Practices Guidelines provide guidance on preparing and structuring your Technical Documentation. Following these will ensure your submission to BSI is complete and thorough.

CE-Excellence: Technical Documentation Review

Our CE-Excellence: Technical Documentation Review services deliver the efficiency you need to be both competitive in the market and maintain confidence through our robust technical reviews.

CE-Standard

Our standard service reviews are completed by experienced BSI Product Experts, giving you confidence in the review.

CE-Dedicated

This service allows you to schedule your Technical Documentation review with a dedicated BSI Product Expert.

Five steps to getting your product to market

Step 1

BSI prepares a quotation

A BSI representative meets with your organization to discuss your needs and the available solutions. We will also discuss the best service for your requirements.

Step 2

BSI performs a conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your organization throughout the process. A QMS audit will then be performed and all Technical Documentation reviewed by one of our experienced technical experts.

Step 3

Certification decision

Successful assessment leads to your BSI scheme manager recommending certification of your product. The BSI Certification Decision team will then review the recommendation and, if satisfactory, approve certification.

Step 4

Issue certificate

Upon successful certification, you will be issued with a certificate. You will then be able to CE mark your product and launch to market.

Step 5

Certification maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance. Your BSI scheme manager will be able to support you with any queries you might have.

Talk to BSI today

Call: **+91 11 2692 9000**

Visit: **bsigroup.com/IVD**

and start your journey

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