



BSI IVD Service Benefits:

Combined Industry and Regulatory *In-house* Expertise in a Wide-Range IVD Products

Predictable, Fast, Efficient and Professional Service

Speed-to-Market Programs

Full Scope in all 3 CE marking Medical Device Directives

Using Industry Leaders for Batch Testing Making the Transfer Process Timely and Seamless

Understanding how to Navigate the Regulatory Landscape

Responsiveness and Easy Access to *In-house* Expertise

BSI Healthcare is a well respected Notified Body dedicated to providing robust regulatory and quality management reviews for medical device manufacturers around the world.

BSI Introduces a NEW In Vitro Diagnostic CE Marking Service

Fully Resourced with Diversity and Depth of Expertise to Meet the Challenges of Today's IVD Directive and the Regulatory Demands of Tomorrow

BSI is expanding its offering by introducing a fully resourced, professional *in-house* In Vitro Diagnostic (IVD) CE Marking Service. BSI Healthcare built this new service on the same successful foundation that has made us a leading Notified Body—with a worldwide reputation for delivering expert, fast, efficient and predictable services.

It is essential that a Notified Body can support clients across device categories. By the extension of our scope, BSI enables customers to work with one organization for their regulatory needs including Medical Devices Directive (MDD), Active Implantable Medical Devices Directive (AIMDD) and In Vitro Diagnostic Directive (IVDD).

What is an In Vitro Diagnostic Device?

In-vitro Diagnostics are an essential and fast growing part of healthcare. IVDs are medical devices and accessories used to perform tests on samples, such as blood, urine, tissue, taken away from the human body to help detect infection, diagnose a medical condition or prevent disease.

There is a broad spectrum of IVD devices from very simple tests to cutting edge DNA technology. This includes reagents, calibrators, control materials, kits, software and related instruments, whether used by themselves or as a part of a combination.

Aim of the IVDD Directive and Market Access

The In Vitro Diagnostic Directive (IVDD) 98/79/EC sets the regulatory requirements needed to gain access to the European Economic Area (EEA), which comprises the 27 member states of the European Union plus additional countries. The aim of the Directive is to promote free trade by safeguarding the health and safety of patients, users and third parties by ensuring that the manufacturer meets quality standards and demonstrates their products perform as intended. The IVD manufacturer is solely responsible for complying with the Directive; however, the use of a Notified Body may be required to assess CE marking conformity before placing the device on the European market.

Team of *In-house* IVD Experts

BSI has an exceptional team of *in-house* experts with an average of 17 years IVD industry and regulatory experience in a wide-range of products. These leading experts have worked on all aspects of the product life cycle, including R&D, manufacturing and quality to meet the demands of this exciting marketplace—both now and in the future. Whether your product is simple or complex, BSI promises to deliver professional, fast and responsive services with the highest quality and most efficient reviews possible.

When Do You Need a Notified Body?

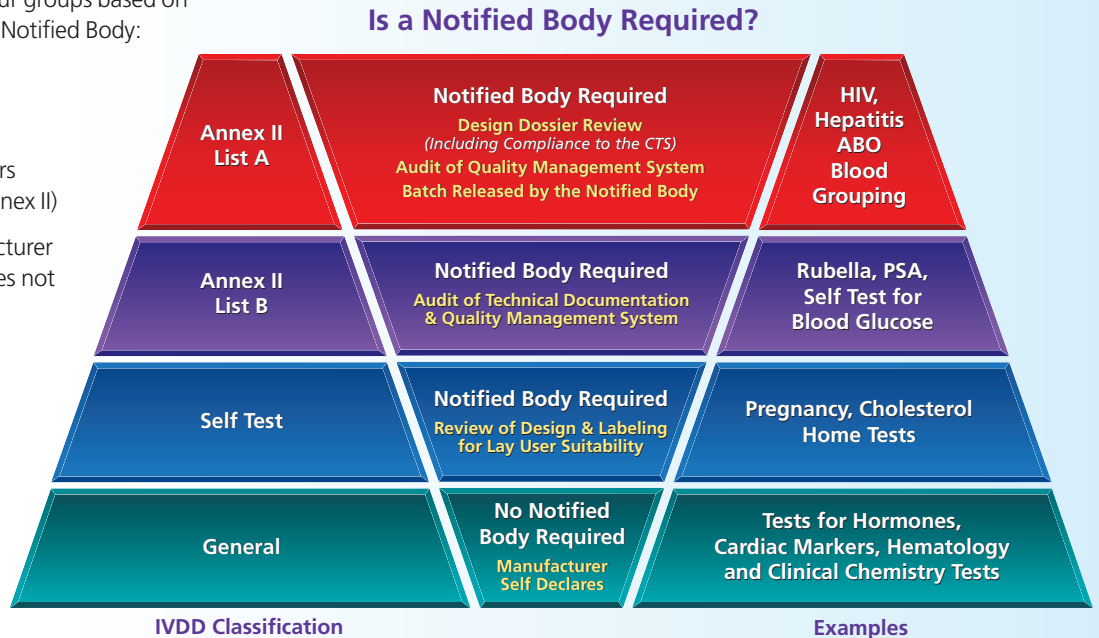
The degree of involvement of a Notified Body, an independent third party, is generally proportional to the risks associated with a particular category of devices. Higher risk devices require a Notified Body to assess compliance, prior to the manufacturer making their Declaration of Conformity to the Directive and placing the product on the market in Europe.

The Directive classifies IVDs into four groups based on perceived risk. The first 3 require a Notified Body:

- 1) Annex II List A - High Risk
- 2) Annex II List B - Moderate Risk
- 3) Self-Testing - suitable for lay users (excludes self-test covered in Annex II)
- 4) General - Low Risk, the manufacturer self-declares conformity and does not require a Notified Body.

The Diagram summarizes this relationship.

BSI has a comprehensive scope of IVD accreditations to meet your product needs.



BSI Healthcare

When choosing BSI you can rely on our five core values:

Product Expertise – our diverse and experienced team brings in-depth knowledge and understanding of complex medical device technologies.

Speed-to-Market – providing flexible solutions for manufacturers needing accelerated pathways to global markets.

Global Access – we operate in over 100 countries with more than 100 years of experience.

Confidence – our rigorous review process combines speed with experience, integrity, independence and predictability.

Partnership – we focus on establishing a partnership with each client so we can work together to meet their goals.

Full Service Notified Body

- CE Marking
 - Medical Devices Directive (MDD)
 - Active Implantable Medical Devices Directive (AIMDD)
 - In Vitro Diagnostic Directive (IVDD)
- ISO 13485 Quality Management
- Health Canada CMDCAS
- Japan PAL
- FDA 510K Third-Party Programs
- Training and Standards
- Supply Chain Security
- Business Continuity Management
- Additional Services Available

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