Your partner
in progress

In Vitro Diagnostic Medical Devices

EU Notified Body, UK Approved Body and Auditing Organization Expertise

As a manufacturer of a In Vitro diagnostic (IVD) medical devices, you must ensure that you meet the relevant regulatory requirements before placing your product onto the market.

Europe: Medical Device Regulation **(MDR)(EU) 2017/745** and In Vitro Diagnostic Regulation **(IVDR) (EU) 2017/746**

Great Britain: Medical Devices Regulations **(UK MDR 2002)**

Global: Medical Device Single Audit Program **(MDSAP)**

It is critical to work with a trusted EU Notified Body or UK Approved Body or Auditing Organization that understands the industry and has the experience to review and confirm your product's readiness for market - efficiently, promptly and robustly. Our Technical Specialists have extensive experience in IVD medical devices and can support you through the process of certifying your device.

BSI Group The Netherlands B.V. (2797) is a leading full-scope Notified Body; we review medical devices to ensure that they conform to the requirements of the European Directives and Regulations.

BSI Group Assurance UK Ltd (0086) is a full-scope UK Approved Body that provides Conformity Assessments under the UKCA scheme.

BSI Group America Inc. is a recognized MDSAP Auditing Organization.

What is an IVD medical device?

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. IVD medical devices must have a medical application or purpose.

See (EU) 2017/746, Article 2

For additional information, visit **our IVDR webpage**

Product range covered and more

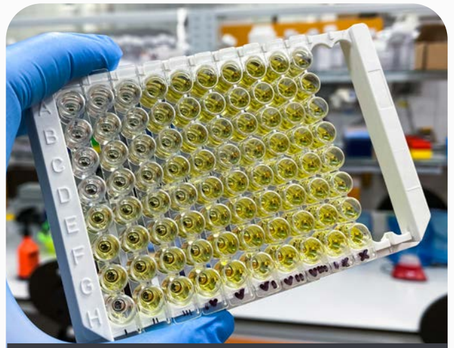
Blood glucose monitors

Clinical chemistry assays

Self-tests

Companion diagnostics

Human genetic testing



Immuno assays

Cancer diagnostics

Blood grouping

Meet our IVDR Team

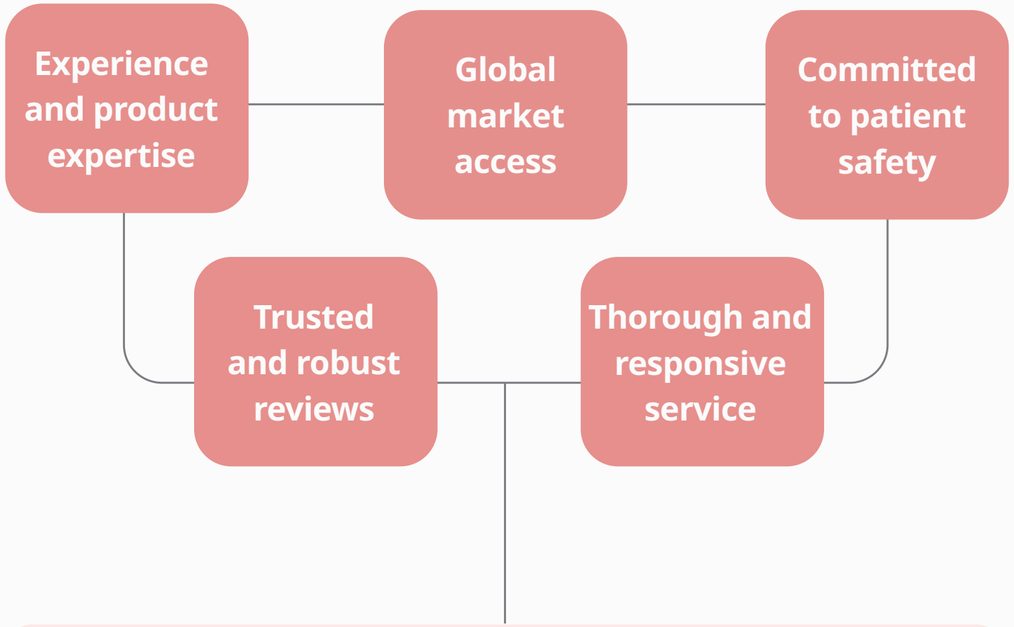
With an avarage of over 20 years of combined experience, our IVD team has a broad range of industry and regulatory knowledge, including product design and development, manufacturing, testing and regulatory expertise.

Thanks to our knowledgeable team, we are able to offer CE certification under the EU IVDR and UKCA certification under the UK MDR 2002 for a wide range of IVDs. We cover blood glucose monitors, cancer diagnostics, clinical chemistry assays, companion diagnostics, devices for blood grouping, self-tests, near-patient testing devices and much more.

> "We know that IVDs come in all shapes and sizes and that navigating this highly regulated industry is challenging for many manufacturers. Our knowledgeable technical and clinical experts understand the context in which these devices are used. This allows us to navigate the IVD regulatory landscape with pragmatism by keeping patient safety at the forefront, while offering to manufacturers a reliable and robust conformity assessment process.

Elizabeth Harrison
Global Head of IVD,
Medical Devices, BSI

Why choose BSI



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

Experience and product expertise

In the complex and ever-changing medical device industry, support from experienced, professional and well qualified technical specialists is critical.

BSI Medical Devices consists of a team of over 1000 professionals including technical experts and internal clinicians with expertise encompassing the full range of medical devices and management system standards.

Committed to 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 and robust conformity assessments, evaluations and certifications.

Thorough and responsive service

We truly understand the challenges medical devices manufacturers face in bringing compliant products to market efficiently and safely.

We offer standard and dedicated review services providing you with the efficient pathways to bring your device to market.

Global market access

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

BSI The Netherlands (2797) is a leading Notified Body. We review medical devices to ensure that they conform to the requirements of the European Directives and Regulations.

BSI UK (0086) is a UK Approved Body able toprovide conformity assessments under the UKCA scheme.

BSI is a recognized Auditing Organization, providing Quality Management System certification through Medical Device Single Audit Program (MDSAP).

BSI is a Conformity Assessment Body for EN ISO 17021-1 (EN-ISO 9001, ISO 14001, ISO 13485) as accredited by the Dutch Accreditation Council (RvA) and the UK Accreditation Service (UKAS).

Trusted and robust reviews

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

Five steps from product-to-market

1

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.

2

Conformity assessment

A dedicated BSI scheme manager will be assigned to you, supporting your company throughout the process.

A QMS Audit will then be performed and all Technical Documentation reviewed by one of our experienced technical specialists.

3

Certificate 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.

4

Issue certificate

Upon successful conformity assessment you will be issued with a certificate.

You will then be able to CE/UKCA mark your product and launch to market.

5

Certificate maintenance

On-going surveillance audits and reviews are required to monitor for continued compliance.

Your BSI scheme manager will support you with any queries you might have.

How BSI supports your market readiness

Readiness

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

Worldwide Access

We offer a wide range of regulatory and quality management programs that work cohesively for international compliance. BSI is an accredited Conformity Assessment Body for Quality Management Systems against ISO 17021-1with ISO 13485, ISO 9001 and ISO 14001 in its scope.

BSI Group The Netherlands B.V. (2797) is a leading Notified Body achieving full-scope designation under MDR and IVDR.

We are a recognized certification body in Japan, Malaysia, Singapore. BSI Group The Netherlands B.V. (2797) is a recognized "Notified Body partner" in Taiwan's Technical Cooperation Programme (TCP), and a recognized MDSAP auditing organization for all participating regulatory authorities.

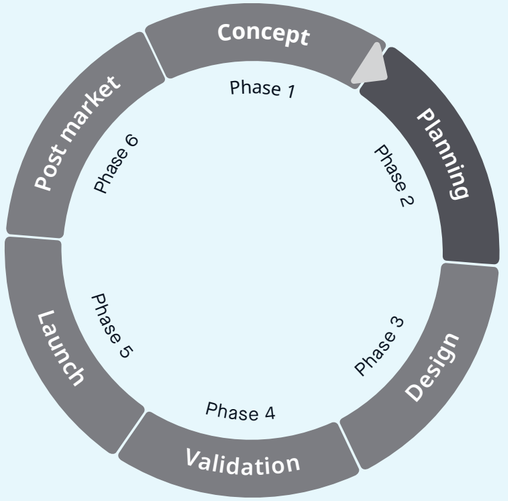
BSI Transfer

We offer a seamless transfer to our services providing comprehensive support to ensure minimal disruption to your company.

Additional Services

- **Access to more than 34,000 standards** and related products, as well as online guidance documents.
- **Expert training** online or face-to-face through our public training courses.
- **Regulatory updates and newsletters** focusing on industry changes, helping you to plan for the future.
- **Webinars** delivered by our experts on regulatory issues.
- **Comprehensive whitepapers** providing the latest insights on key industry topics.

The product lifecycle



Considering 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.

Our consolidated clinical and regulatory planning will support 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

Navigating your compliance to the IVDR

The IVDR (EU2017/746) which replaced the IVDD (98/79/EC), entered into force on May 2017. Manufacturers must ensure their Technical Documentation and processes meet the new requirements for placing IVDs on the EU market

Manufacturers are invited to apply to a Notified Body as soon as possible to ensure compliance with the regulation.

For additional information on significant device changes that may trigger an IVDR application you can consult **MDCG 2022-6**.

Starting the certification process?

Transitioning to IVDR?

Transferring to BSI your existing certification?

From the experts

The process of CE or UKCA marking for IVD medical devices can be challenging. Strong and statistically relevant clinical evidence, demonstrating the safety and performance of your device, is essential to ensure a successful outcome of your IVDR application.

IVDR Best Practices Guidelines to support you

Conformity Assessment guidance to meet IVDR requirements

Continued access to our technical experts throughout your submission

CE/UKCA Excellence

Technical Documentation Review Services deliver the efficiency you need to be competitive in the market and maintain trust.

Standard

Access to technical review timeline after Technical Documentation submission.

Dedicated

Technical review planned up-front to Technical Documentation submission.

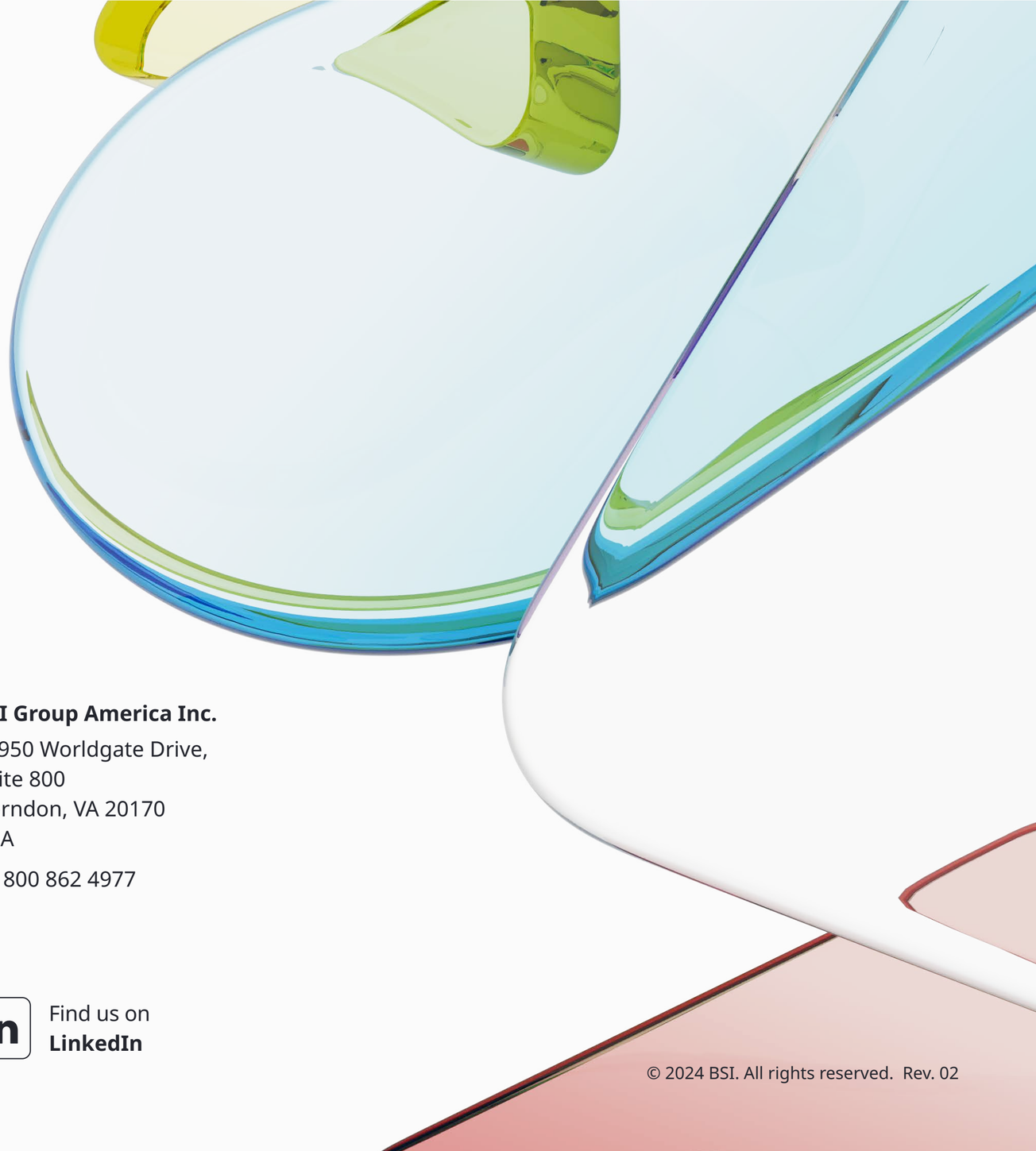
Talk to BSI today and start your journey

Get in touch

Whether you are starting the certification process, looking to transfer or need to discuss your options, we can guide you through the process.

Request a quote

Your partner in progress



BSI Assurance UK Ltd (0086)
Kitemark Court,
Davy Avenue, Knowlhill,
Milton Keynes, MK5 8PP
United Kingdom

+44 345 080 9000

BSI Group The Netherlands B.V. (2797)
Say Building,
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

+31 20 346 0780

BSI Group America Inc.
12950 Worldgate Drive,
Suite 800
Herndon, VA 20170
USA

+1 800 862 4977

Find our services at
bsigroup.com/medical

Email us at
medicaldevices@bsigroup.com

Find us on
LinkedIn