Your partner
in progress

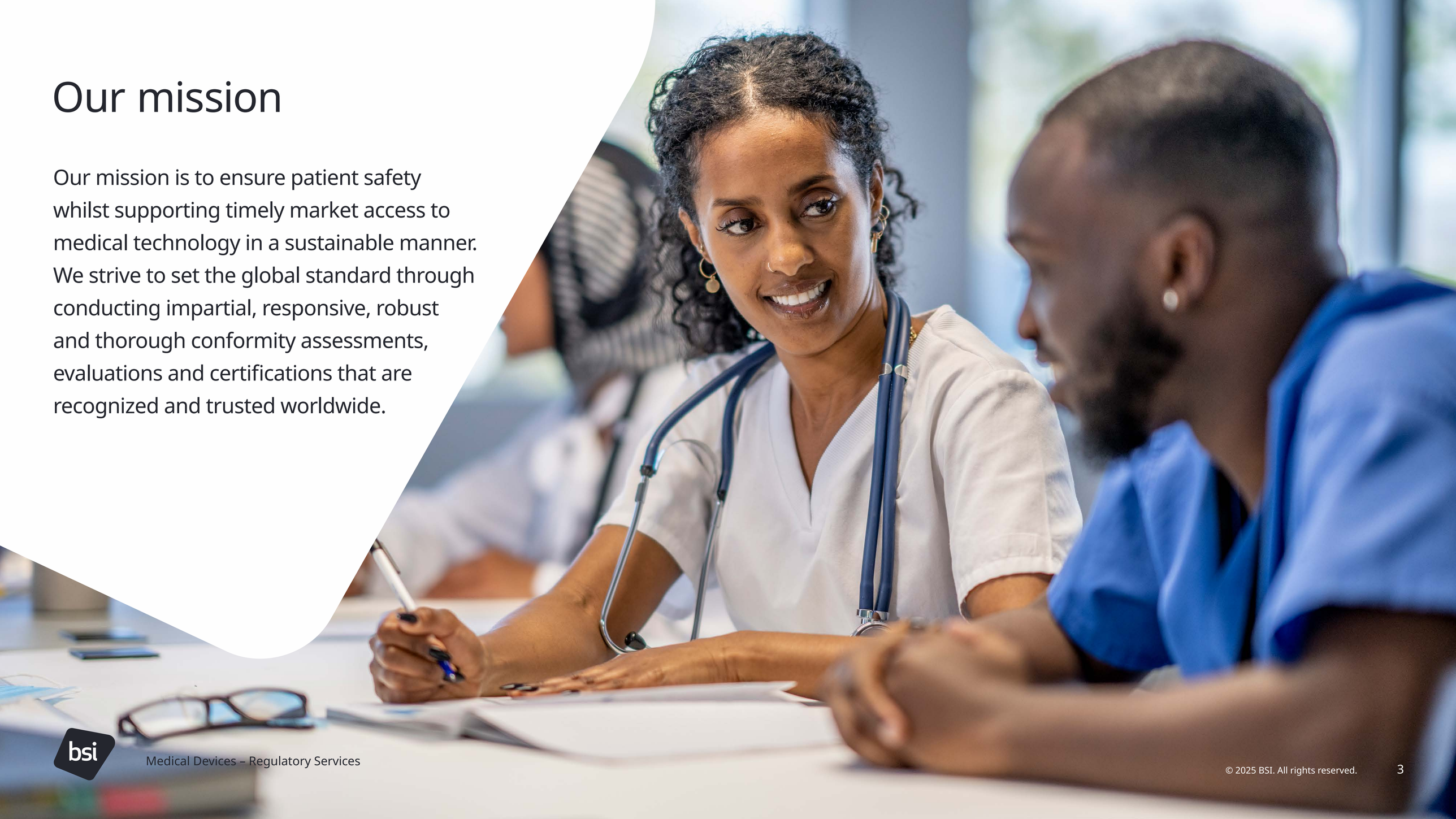
Medical Devices

Regulatory Services

Contents

Our mission

Our mission is to ensure patient safety whilst supporting timely market access to medical technology in a sustainable manner. We strive to set the global standard through conducting impartial, responsive, robust and thorough conformity assessments, evaluations and certifications that are recognized and trusted worldwide.



Maintaining quality and delivering excellence

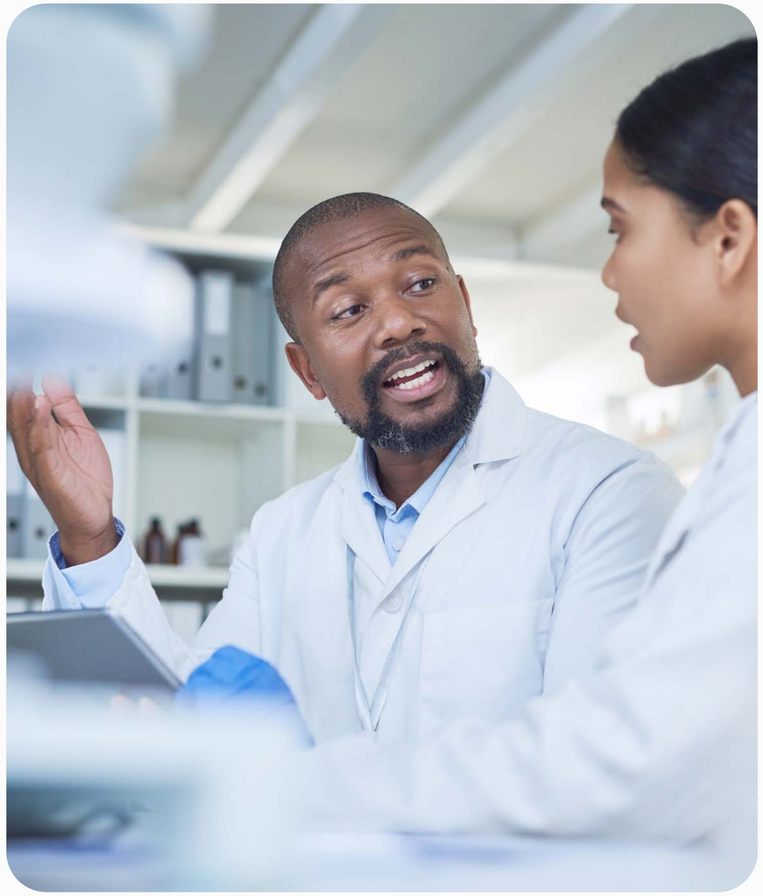
BSI consists of 5,000 people supported by 12,000 industry experts in more than 193 countries. Our regulatory services combined with our world-leading experience provide efficient pathways to place your device on the market.

BSI Group The Netherlands B.V. (2797) is a full scope Notified Body; we review medical devices to ensure they comply with the requirements of the European Regulations.

BSI Assurance UK Ltd (0086) is a full scope Approved Body able to provide conformity assessments under the UKCA scheme.

We also are

- An accredited ISO 13485 Certification Body.
- A recognized Auditing Organization under the Medical Device Single Audit Program (MDSAP).
- A Conformity Assessment Body and a registered Certification Body in many global markets.



BSI is continuously committed to providing manufacturers with efficient pathways to place medical devices on the market. We are the first Notified Body and Approved Body publishing **capacity and lead times for MDR, IVDR and UKCA** applications and Conformity Assessments.

Beyond supporting well-established manufacturers, we offer a wide range of resources to support SME's by increasing their knowledge on key regulatory topics for market readiness. Globally, more than 85% of manufacturers we work with across all regulatory certification services are SMEs. We continue to accept new applications, to refine our supporting tools and to increase the number of SMEs we work with.

Some entities we operate with

Technologies we assess

The benefits of working with experienced, professional and well qualified experts cannot be overstated in the complex and ever-changing medical device industry.

Our collaborators are experienced in all aspects of the product lifecycle, including research and development, manufacturing, and quality assurance. We offer specialized in-house expertise in areas ranging from sterilization processes, and animal tissue utilization to combination of medical device products.

Our core competencies and unique skills are calibrated to handle our customer's extensive portfolio of medical technologies. Our technical experts understand the specifics of these complex devices through their full lifecycle and have experience encompassing the full range of medical devices regulations and management system standards.

Click on the images to find out more

Active implantable

SaMD

Vascular

General

In vitro diagnostic

Cybersecurity

Active

Microbiology and sterile

Medicinal and biologic

Ortho and dental

Artificial intelligence

Clinical expertise

BSI has built a team of internal experts. This allows for an efficient and effective Clinical Evaluation Assessment.

Our experts own extensive experience in the field, undergo comprehensive training and regular clinical practice to ensure safe and pragmatic devices evaluation.

This allows us to meet our full code designation of all types of devices from diagnostics to therapeutic, including cosmetic devices per Annex XVI.

More than 13 internal clinicians

More than 70 internal clinical evaluation specialists

Your path through our experts

Commercial Contact

- Liases with the technical team on your application
- Arranges your quote
- Provides information on additional services required

Technical Specialist

- Performs conformity assessment
- Has relevant expertise to your device
- Maybe your Scheme Manager

Client Manager

- Conducts onsite assessment of your Quality Management System (QMS)
- Provides report of findings for Certification Review
- Conducts surveillance audits

Microbiologist

- Performs specialist microbiology assessments
- Has the expertise to review sterility aspects of your products and manufacturing systems

Scheme Manager

- Coordinates and oversees certification
- May assess your technical documentation

Planner

- Arranges QMS visits
- Assigns your Client Manager for each assessment

Operations management team

- TDRs timelines project management and progress monitoring
- Management of clients' TDRs portfolio and meetings

Client Services Coordinator

- Supports the Technical Specialist
- Provides administrative support

Certification Specialist

- Manages your ISO 13485 only certification

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 persistent compliance.

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

Click to continue the lifecycle

The product lifecycle

Where are you in the medical device product development lifecycle?

An understanding of the complex clinical and regulatory requirements early in the product lifecycle matched with consolidated planning will help you in maximizing resources and reducing the risk of expensive redevelopments later in the lifecycle.

Phase 1: Concept

Initial evaluation of possible development of commercial product

Is it a medical device?
Intended use
Initial risk analysis
Product definition and intellectual property
Commercial plan
Potential markets and routes
Draft regulatory strategy
Personnel/resource requirements

Phase 2: Planning

Definition of design input based on customer needs and technical requirements

Concept development
Prototype analysis
Initial testing
Design file and risk analysis
User feedback
Commercial and market strategy
Regulatory strategy
Quality Management System
Project plan

Phase 3: Design

Development of product design, manufacturing process, and verification and validation

User feedback
Manufacturing process
Design verification and validation
Risk management
Draft Technical Documentation
Regulatory strategy
Product claims and branding
Regulatory requirements

How BSI can support you

EU CE and UKCA marking
QMS ISO 13485
MDSAP
Global market access certification
Training Academy
Business and technical standards
Compliance Navigator

QMS ISO 13485
MDSAP
Training Academy
Business and technical standards
Compliance Navigator
QMS ISO 13485 pre-assessment

The product lifecycle

The stage that represents where your product is in the product lifecycle can help you identify additional considerations you should look into.

Click to restart the lifecycle

Phase 4: Validation

Final validation of manufacturing process and preparation for product introduction

- Market plan/forecast
- Process validation
- Clinical validation
- Product claims
- Final labelling
- Regulatory submission
- Product reimbursement
- EU CE and UKCA marking
- Global market access certification

Phase 5: Launch

Product launch

- Regulatory approval
- Sales and clinician training
- Launch product to market
- Individual country reimbursement approval

Phase 6: Post-market

Post market surveillance

- Post-market surveillance
- Post-market clinical follow-up
- Complaints and adverse events
- Product improvements
- Process improvements
- External body audits
- Market performance
- New market launches

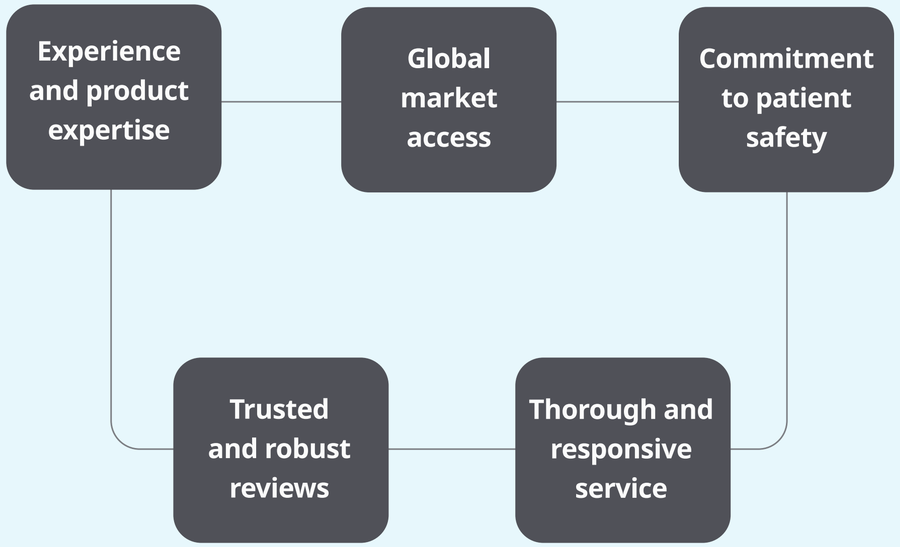
How BSI can support you

- EU CE and UKCA marking
- QMS ISO 13485
- MDSAP
- Global market access certification
- Training Academy
- Business and technical standards
- Compliance Navigator

- QMS ISO 13485
- Global market access certification
- Training Academy
- Business and technical standards
- Compliance Navigator

Our excellence pathways

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



Structured dialogue

As a leading Notified Body, for over 20 years, BSI has been offering Structured Dialogues to enhance the efficiency and predictability of the conformity journey through all its phases.

While respecting the independence and impartiality of the Notified Body, our approach to structured dialogue is highly collaborative. Various roles within BSI, including technical specialists, the commercial team, and scheme managers, engage at different stages of the process.

Pre-application

Examples of Dialogue topics

- Application process
- Conformity assessment process
- Lead times
- Project plan and client readiness
- Client information
- Indicative costs
- Organizational structure
- Transferring to BSI: the process

Application

Examples of Dialogue topics

- Commercial contract management
- Project management
- Client engagement
- Certification process
- Submission requirements
- Change management

Our Structured Dialogue is suitable for various types of organizations including: start-ups, SMEs, large organizations, global enterprises

Post-Certification

Examples of Dialogue topics

- Ongoing technical and regulatory dialogue
- Ongoing Change Management Activities
- Project Management and general Client Support
- Compliance Management
- Recertification

Conformity assessment

Examples of Dialogue topics

- Submission requirements
- Conformity assessment
  - Leveraging previous assessments
  - Conformity assessment activities and associated timelines
  - Clarification on assessment findings and missing data
- Completeness check
- Rounds of questions

BSI CE and UKCA Excellence Programs are designed to support manufacturers seeking timely and effective market access. Our services combine efficiency with the integrity, independence, and the thoroughness you expect from BSI.

Standard

The Standard review service allows you to work closely with your assigned BSI Product Expert on your product certification. These reviews are conducted remotely, with communication between you and your BSI Product Expert
via phone and email as required.

Scheduling of reviews	The Technical Review will be scheduled based upon date of receipt of technical documentation.
Manufacturers touchpoints	Meetings by request after Round 1 questions sent. Dialogue between manufacturer and review is by request.
Rounds of questions	Maximum three formal rounds of questions with a fourth by exception (subject to approval).
Review question timing	Response date provided by the reviewer per BSI procedure and accepted by the manufacturer.

Dedicated

The Dedicated review service allows a technical document review to be booked in advance. It is conducted remotely with your BSI Product Expert, who uses your allocated time, to conduct a focused review of your technical documentation. This allows you to interact with your BSI Product Expert, and provide information during the review. By improving the efficiency of the process, this service provides predictability in your review planning.

Scheduling of reviews	The Technical Review will be pre-scheduled based on expected submission date.
Manufacturers touchpoints	Opening/closing meetings. Interactive review integrated into the process. Real time dialogue during the initial review and after each formal round of questions. Additional communication by manufacturer or reviewer request.
Rounds of questions	Questions/clarifications any time during the initial review. Formal questions, if needed, sent at the end of the initial review. Maximum three rounds of questions with a fourth by exception (subject to approval).
Review question timing	Response date aligned between the manufacturer and the reviewer (recommended not to exceed 30 business days). Responses reviewed once received without undue delay.

Note: Our services do not guarantee an EU/UKCA certificate will be issued or that it will be issued within a certain number of working days but they are based on completing the review process with either a positive or negative recommendation. All type of reviews exclude time under consultation (e.g., Clinical Evaluation Consultation Process - CECP, devices utilizing animal tissue derivatives or medicinal substances which require Competent Authority involvement).

Interactive Dedicated Review

Dedicated interactive reviews foster flexibility, efficiency, predictability and transparency.

This review service consists of a remote technical documentation assessment which is performed interactively between manufacturers and reviewer(s) throughout the assessment to provide a collaborative, transparent and predictable service. The assessment dates, including any follow-up dates required to address open questions are planned and scheduled in agreement with the manufacturer.

This type of review is recommended to be delivered interactively to maximize all the benefits of the service. If the client chooses a less interactive review but still wishes to benefit from pre-scheduling and dedicated reviewer predictability, the review can be delivered fully remotely. There is no additional cost for an interactive dedicated review compared to a non-interactive dedicated review.

CE reviews eligible	All reviews, excluding PSUR and SSCP.
Scheduling of reviews	Pre-scheduled based on expected submission date.
Horizontal reviews	Run in parallel or scheduled to start in advance where consultations are required.
Review coordination, opening and closing meeting	Integrated into the process. All reviews and manufacturer representatives encouraged to participate.
Manufacturer touchpoints	• Opening/closing meetings. Interactive review integrated into the process. • Real time dialogue during the initial review and after each formal round of questions. • Additional communication by manufacturer or reviewer request.
Initial phase of the review	• Scheduled window of time (proportional to review duration). • Interactive chat /voice/video via MS Teams.
Rounds of questions	• Questions/clarifications any time during the initial review. • Formal questions, if needed, sent at the end of the initial review. • Maximum three rounds of questions.
Review question timing	• Response date aligned between manufacturer and reviewer recommended not to exceed 30 business days. • Responses reviewed once received without undue delay.

Note: Our services do not guarantee an EU/UKCA certificate will be issued or that it will be issued within a certain number of working days but they are based on completing the review process with either a positive or negative recommendation. All type of reviews exclude time under consultation (e.g., Clinical Evaluation Consultation Process - CECP, devices utilizing animal tissue derivatives or medicinal substances which require Competent Authority involvement).

Transfer to BSI

Having confidence in your Notified Body and Approved Body to deliver an efficient and thorough conformity assessment under the applicable **EU** and **UK** legislations is crucial.

Our approach focuses on open communication from the very beginning and your application will be supported by a dedicated team of experts. We offer a seamless transfer to our services providing comprehensive support to ensure minimal level of disruption.

CE certificate	UKCA certificate	ISO 13485 certificate
Your initial application	Your initial application	If you are transferring your ISO 13485 certification to BSI, we will conduct a pre-Transfer review to assess your organization, current certification and compliance
Pre-transfer initial documentation review	Pre-transfer initial documentation review	Pre-transfer review
Pre-transfer Technical Documentation and QMS review, as needed: • Onsite QMS review • MDR/IVDR Technical Documentation review	Pre-transfer Technical Documentation and QMS review, as needed: • Onsite QMS review • UK Regulation Technical Documentation review	Certification review
Recommendation for acceptance of transfer: • Certification Panel review • Contact previous Notified Body • Labelling transition	Recommendation for acceptance of transfer: • Certification Panel review • Contact previous Approved Body • Labelling transition	Certification decision
Transfer completion	Transfer completion	Certificate awarded
		Continuous Audit Visit cycle resumes

Note: The transfer process to BSI does not imply a full conformity assessment for the devices covered by the certificates to be transferred. BSI issues its own certificate(s) largely based on conformity assessments carried out, and certificates issued by the previous Certification Body. BSI reserves the right to undertake further assessments and require corrective actions at any time after the transfer of certification, if BSI becomes aware of any issues that could affect the safety or performance of the devices covered by the transferred certificates.

Our Regulatory Services portfolio

Our comprehensive portfolio offers you a wide range of proven regulatory and quality management services to support you in bringing compliant devices to market efficiently and safely.

CE certification

CE marking is the medical device manufacturer's claim that a product meets the General Safety and Performance Requirements (GSPR) of all relevant European Medical Device Regulations. It is a legal requirement to place a device on the market in the European Union.

We review your medical device to ensure conformity against **MDR** and **IVDR** by offering a range of flexible product review services providing you with efficient pathways to bring your device to the market.

To know more visit out dedicated **MDR** and **IVDR** webpages.

MDR Resources

MDR Transition Guidance

MDR Transition FAQs

MDR Timeline

Transfer of Appropriate surveillance (EU) 2023/607

MDR Technical Documentation Best Practice Guidance

MDR Conformity Assessment Routes

IVDR Resources

IVDR Transition Guidance

IVDR Transition FAQs

IVDR Timeline

IVDR Conformity Assessment Routes

IVDR Technical Documentation Best Practice Guidance

EUDAMED

UKCA certification

UKCA marking is the medical device manufacturer's claim that a product meets the Essential Requirements (ER) of the UK Regulation and is a legal requirement to place a device in the UK market. We review your medical device to ensure conformity against UK legislation by offering a range of flexible certification services providing you with efficient pathways to bring your product to market.

UKCA Resources

UKCA Timeline

UKCA Marking with BSI

UKCA Roadmap

UKCA FAQs

To know more, visit our **UKCA dedicated webpage**.

Article 16(4) Certification (MDR & IVDR)

BSI is designated to issue article 16(4) certificates for all types of medical devices and IVDs that are subject to activities laid down in Article 16(2).

Article 16(3) of MDR and IVDR establishes requirements for the QMS that distributors and importers must implement when carrying out specific relabeling and repackaging activities for devices that have already been placed on the market. Article 16(4) mandates that these entities obtain certification from a Notified Body to verify that their QMS meets the regulatory requirements outlined in Article 16(3) and detailed in MDCG 2021-23.

For whom is Article 16(4) Certification relevant?

This certification applies to importers and distributors operating in the EEA who engage in the specific relabeling and repackaging activities described in Article 16(2), for devices (irrespective of their classification) that are already placed on the market under the MDR or the IVDR.

Examples of relabeling and repackaging activities

- Updating packaging labels
- Translating information provided by the manufacturer (e.g., IFU)
- Adding additional information required to market the device in a specific EU Member State

Article 16(4) certification is not required for:

- Operators subcontracted by manufacturers to perform relabelling or repackaging under the manufacturer's control
- Health institutions or hospitals that break up large device packs into smaller units for internal use
- Legacy Devices under Directive Certification

To know more visit our **dedicated webpage**

Annex XVI

Devices without an intended medical purpose

Annex XVI regulates products without an intended medical purpose, including devices used for aesthetic indications and dual use products.

Annex XVI covers 6 product groups including dermal fillers, cosmetic breast implants, lipoplasty, body sculpting and skin laser equipment, colourednon-corrective contact lenses, and many more.

Thanks to our world-leading experience and expertise we are accepting Annex XVI applications since December 2022. We have already issued numerous Annex XVI certifications and we have more than 60 ongoing applications to date for dermal filling, breast augmentation, lipoplasty, bodysculpting, contact lenses, laser hair removal, dermal abrasion and facelift procedures.

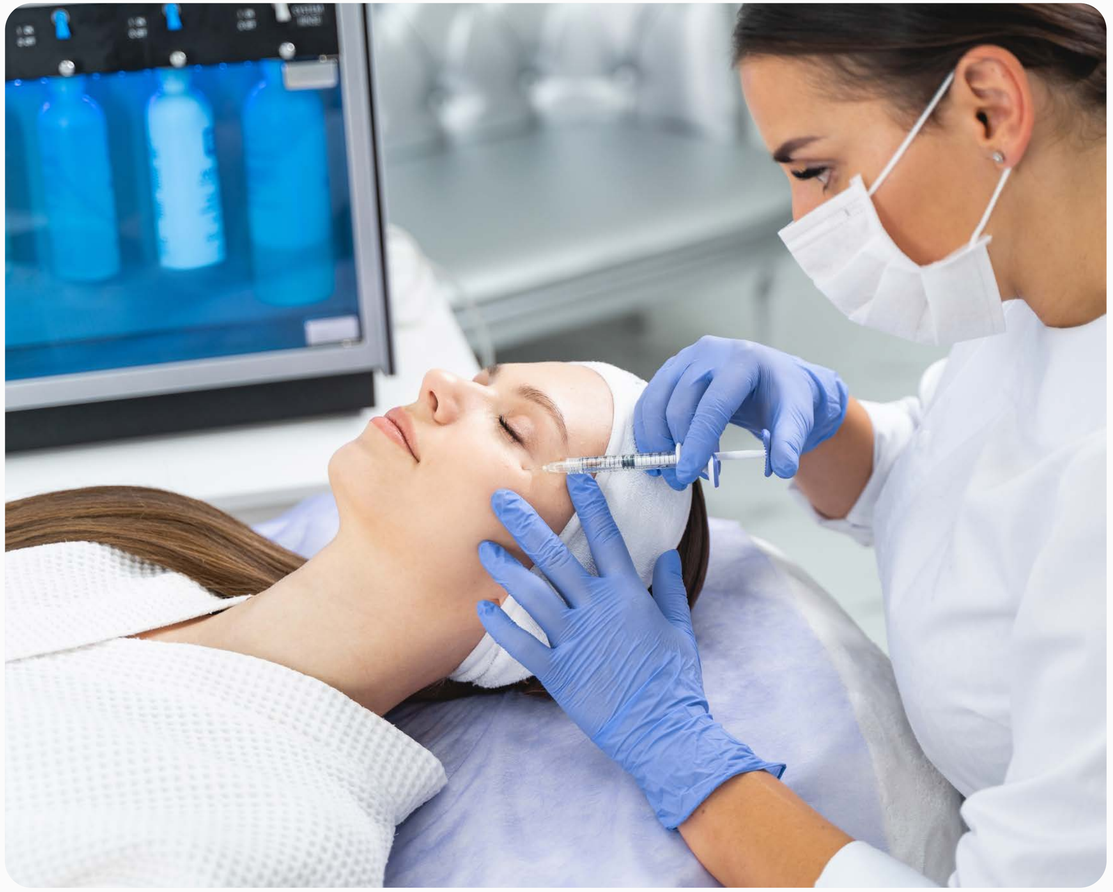
Does your product fall under MDR Annex XVI?

If you want to know more around Annex XVI and its regulatory framework or want to discover how BSI can walk you through your compliance journey, access our dedicated resources.

Resources

Annex XVI Q&A

Annex XVI whitepaper



Quality Management System (QMS)

ISO 13485 certification

ISO 13485 is an effective solution to meet the comprehensive requirements for a medical devices QMS. Adopting ISO 13485 provides a practical foundation for manufacturers to address the regulations and responsibilities, as well as demonstrating a commitment to the safety and quality of medical devices.

Our auditors come with exceptional industry experience, which is maintained and enhanced through BSI internal training and qualification processes. BSI auditors are experts in current state of the art and are constantly trained on new requirements and future changes.

Resources

ISO 13485 QMS certification

ISO 13485 FAQs

To know more, visit our
ISO 13485 dedicated webpage

MDSAP Certification – Medical Device Single Audit Program

MDSAP allows a single audit of a medical device manufacturer's QMS, which satisfies the requirements of multiple regulatory jurisdictions. Through MDSAP, medical device manufacturers can be audited once for compliance with the standard and regulatory requirements of up to five different medical device markets. These are Australia, Brazil, Canada, Japan and United States.

BSI Group Americas Inc. is a recognized Auditing Organization for MDSAP. We have been active since MDSAP inception pilot phase and have already completed a significant number of MDSAP audits, predominantly for world-leading medical device manufacturers and SMEs.

A BSI MDSAP audit can also be combined with assessment for CE, UKCA and ISO 13485.

We have

- A global network of over 200 MDSAP assessors
- More than 240 ISO 13485 QMS assessors worldwide
- In-house Product Experts and auditors
- Access to a dedicated team of technical and clinical specialists

To know more, visit our **MDSAP dedicated webpage** and **brochure.**

BSI’s role in global market access

We work with international regulators to support medical device manufacturers globally in bringing compliant products to market efficiently through the assessment of their medical devices and QMS.

As a leading full scope Notified Body, UK Approved Body and recognized MDSAP Auditing Organization, we hold several other statuses across the globe:

- Registered Certification Body in Japan assessing against PMD Act and Ministerial Ordinance MO 169.
- MDA Registered CAB in Malaysia conducting GDP & Product Verification under the MMD Regulation 2012.
- SAC-accredited Certification Body in Singapore for Medical Devices GDP (GDPMDS SS620) and Medical Devices QMS (ISO 13485).
- Recognised CAB in Egypt by the Egyptian Organisation for Standards for UKAS ISO 13485 accreditation.
- Recognised CAB in South Africa, by SAHPRA, for RvA and UKAS ISO 13485 accredited certificates.
- Recognised TFDA and AAO Partner with respect the Taiwan Technical Co-Operation programme.


Europe


UK


US


Australia


Brazil


Canada


Japan


Malaysia


Singapore


Taiwan


Egypt


South Africa

To know more, visit our **market access** dedicated webpage and **brochure.**

Complementary services

ISO 9001 Quality Management

The world's most widely adopted QMS standard and used by organizations of all sizes. This powerful business improvement tool can help organizations improve customer satisfaction, boost resilience and build for the long term.

ISO 42001 AI Management System

Provides a certifiable AI management system (AIMS) framework in which AI systems can be developed and deployed as part of an AI assurance ecosystem. Applicable to any organization, regardless of size, that provides or uses products or services that utilize AI systems, it not only aligns with the rapid advancement of AI technologies, but also enables companies to leverage these innovations responsibly and ethically.

ISO 45001 Occupational Health and Safety Management

Ensuring employee safety is critical and provides a framework that will help you identify and mitigate risk as well as defend and protect your workforce, reputation and brand.

ISO 14001 Environmental Management

The most established international environmental management system will help you to reduce environmental risk, improve environmental performance and show stakeholders that regulatory requirements have been met.

Electrical equipment systems

The standard provides assurance to electrical engineers, electricians and product designers on safety, performance and compliance for an extensive range of equipment. The standard can support in the assessment of your product for CE marking, which is required to place a product on the market in the European Union.

Cybersecurity

Penetration testing & vulnerability assessment services

BSI can support organizations with their cybersecurity and information resilience through world-leading technical solutions, research and training. Read our brochure on **cybersecurity for medical devices**.

ISO 27001 Information Security Management

An excellent framework to support organizations in managing and protecting their information assets so that they remain safe and secure. ISO 27001 also provides a tool to review and refine your information security management systems for your organization in the future.

Additional resources to support you

Compliance Navigator

Transforming how medical device and IVD device manufacturers manage their regulatory documents to save time, maximise resources and reduce risk. Work smarter with an online platform designed by regulatory experts to help you stay up to date with medtech regulatory requirements.

- Get unrestricted access to an evolving set of regulations and standards.
- Search by device or keyword to find every relevant standard for your product portfolio in seconds.
- Save time performing gap assessments with expert commentary on changes to documents relevant to you.
- Reduce the risk of recall with real-time notifications direct to your inbox about document changes.
- Streamline compliance processes with a user-friendly platform that’s accessible to your entire team.
- Organize, co-ordinate and manage user’s access to documents with increased speed and efficiency.

Take proactive steps towards compliance.
To know more, visit our **dedicated webpage.**

BSI Training Academy

Turn our experience into your expertise

Our training portfolio provides an in-depth understanding on key topics regulating medical devices, IVDs and QMS to increase your knowledge on compliance, implementation, and maintenance of regulatory requirements.

Start your training journey with BSI and grow your knowledge demonstrating competence and compliance with the regulatory landscape, while increasing at the same time your organization knowledge pool.

- Trained 70% of the top 100 medical device companies
- More than 205,000 people trained last year

Our trainers have combined world-leading expertise on global scale. Our highly specialized courses provide an in-depth understanding on key topics regulating medical devices, IVDs and Quality Management System, increasing your knowledge on compliance, implementation, and maintenance of regulatory requirements.

Grow your knowledge from practitioner to professional qualification status demonstrating competence and compliance with the regulatory landscape Take a positive step towards demonstrating this competence by completing a BSI Medical Devices Qualification and obtain a recognized Mark of Trust.

To know more, visit our **Training Portfolio** and **dedicated brochure**.

Stay tuned

Newsletter
You can stay up to date and plan for the future with our news and announcements for medical devices through our regular monthly newsletter.

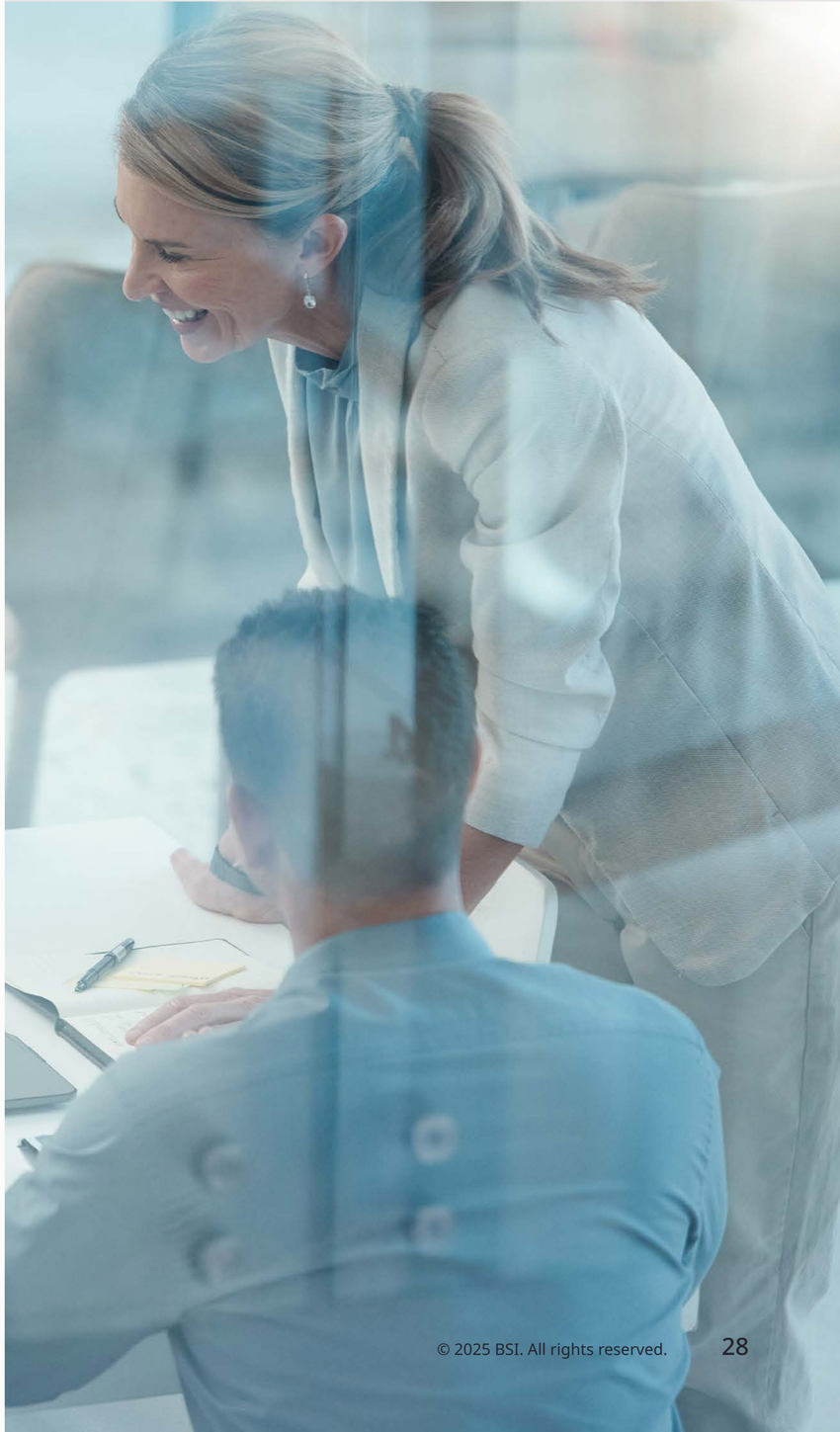
Webinars
Access BSI medical devices webinars portfolio. You can navigate on demand and register for upcoming free live webinars and masterclasses led by our Technical Specialists and Regulatory and Clinical experts. You can choose from an extensive directory on regulations, standards, market access and more.

Whitepapers
BSI offers a comprehensive directory of free whitepapers focused on regulations, standards, clinical investigation and evaluation, surveillance processes and much more. Access our subject matter experts' whitepapers and discover the best practices for the most requested key topics in the medical device sector.

Get in touch

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

Request a quote



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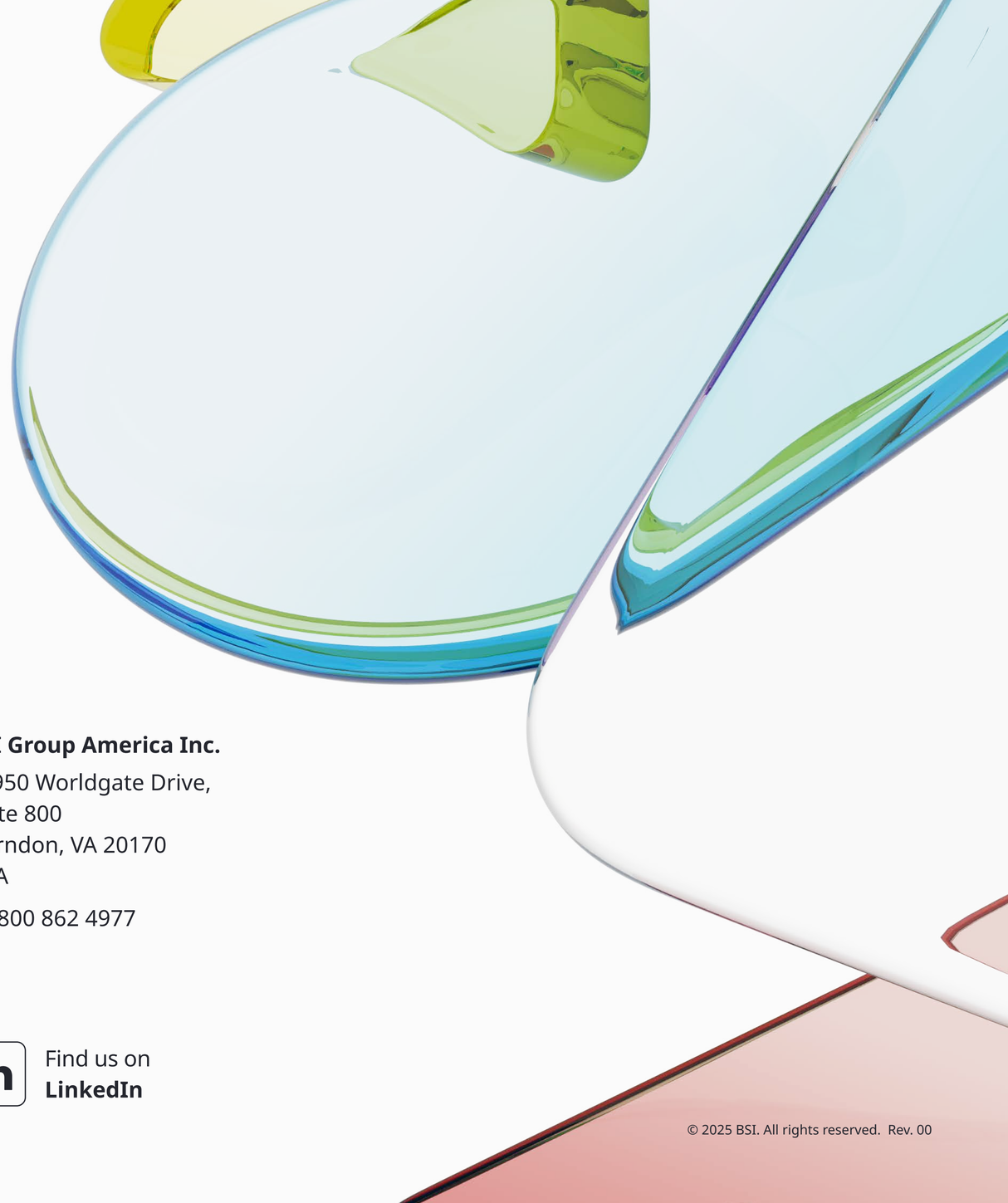

BSI Assurance UK Ltd (0086)

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