Your partner
in progress

Our Excellence Pathways

BSI provides experienced and efficient routes to global markets. Our expertise reaches all aspects of the product lifecycle including research and development, manufacturing, and quality assurance.

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

Standard and Dedicated Reviews

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

We understand that having confidence in your Notified Body and Approved Body to deliver an efficient and robust **CE marking** and **UKCA marking**, and a thorough Quality Management System assessment process (**ISO 13485** and **MDSAP**) 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 marking transfer process

Your initial application

Pre-transfer initial documentation review

Pre-transfer Technical Documentation and QMS review, as needed:

- Onsite QMS review
- MDR/IVDR Technical Documentation review

Recommendation for acceptance of transfer:

- Certification Panel review
- Contact previous Notified Body
- Labelling transition

Transfer completion

UKCA marking transfer process

Your initial application

Pre-transfer initial documentation review

Pre-transfer Technical Documentation and QMS review, as needed:

- Onsite QMS review
- UK Regulation Technical Documentation review

Recommendation for acceptance of transfer:

- Certification Panel review
- Contact previous Approved Body
- Labelling transition

Transfer completion

ISO 13485 transfer process

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 review

Certification review

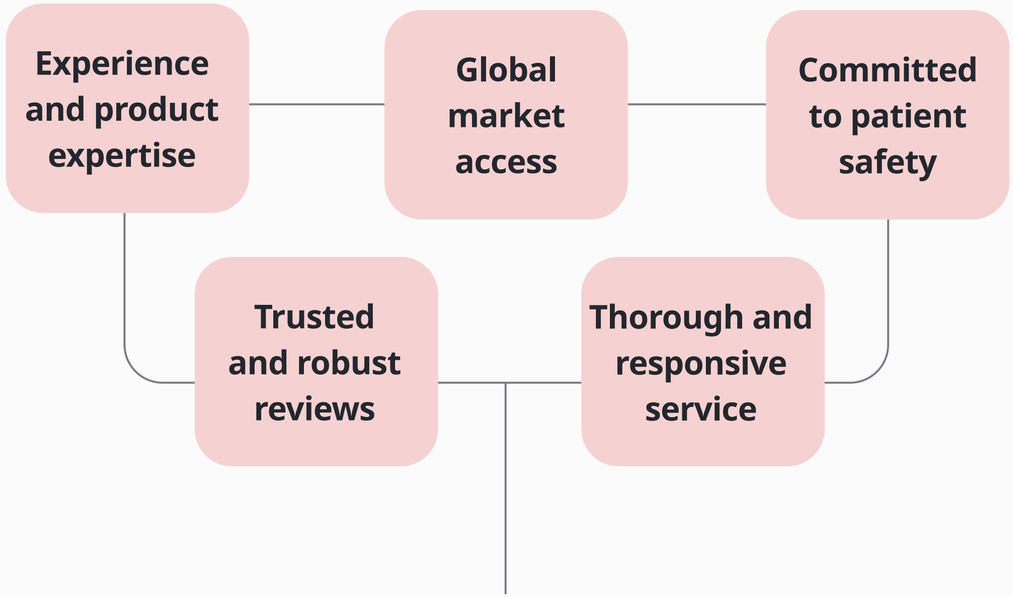
Certification decision

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.

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's medical devices consists of a team of over 1000 professionals including technical experts and internal clinicians expert in 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 to provide conformity assessments under the UKCA scheme.

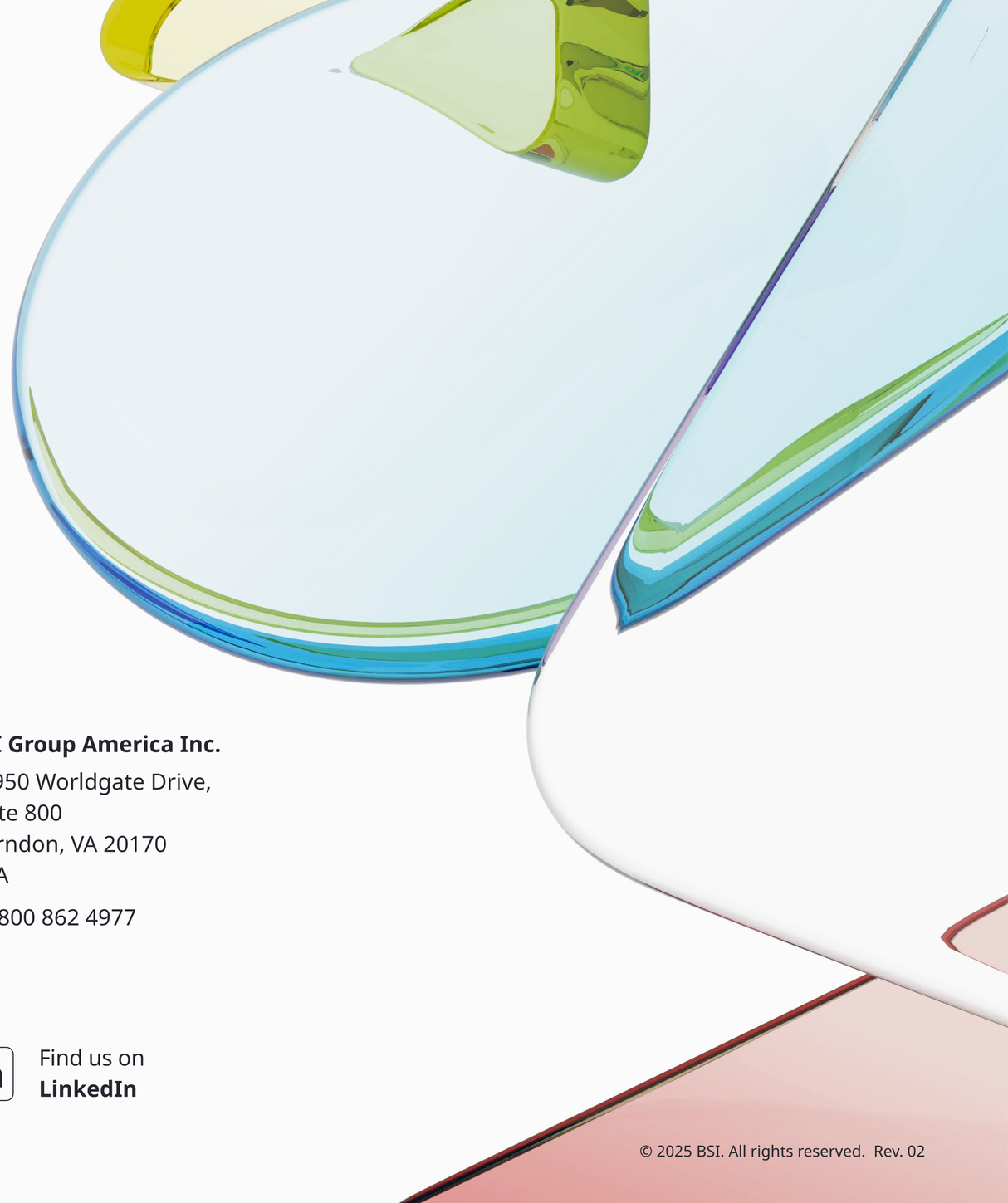
BSI is a recognized Auditing Organization, providing Quality Management System certification through Medical Device Single Audit Program (MDSAP).

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.

Your partner in progress



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