Your partner
in progress

Our Excellence Pathways

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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.

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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.

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.

Assignment of technical review	The Technical Review will be assigned based upon date of receipt of technical documentation
Opening the technical review	None
Scheduling rounds of review	Scheduling is round by round, upon receipt of a full and complete set of responses. The client is given an approximate start date
Review progress/questions	Questions are provided to the client at the end of each review
Closing a review round	List of questions provided to client

Assignment of technical review	The Technical Review will be assigned before the client submits documentation based on readiness of the client
Opening the technical review	Opening meeting with the client
Scheduling rounds of review	Scheduling all rounds up-front. The client is given exact start dates. A minimum time between review tounds to allow for BSI to complete the review and for the manufacture to respond to questions raised
Review progress/questions	Questions are provided to the client throughout the review
Closing a review round	Closing meeting or email to client detailing remaining open questions

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 completeing the review process with either a positive or negative recommendation. CE and UKCA Dediated Review service is not available for devices utilizing animal issue derivatives or medicinal substances.

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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.

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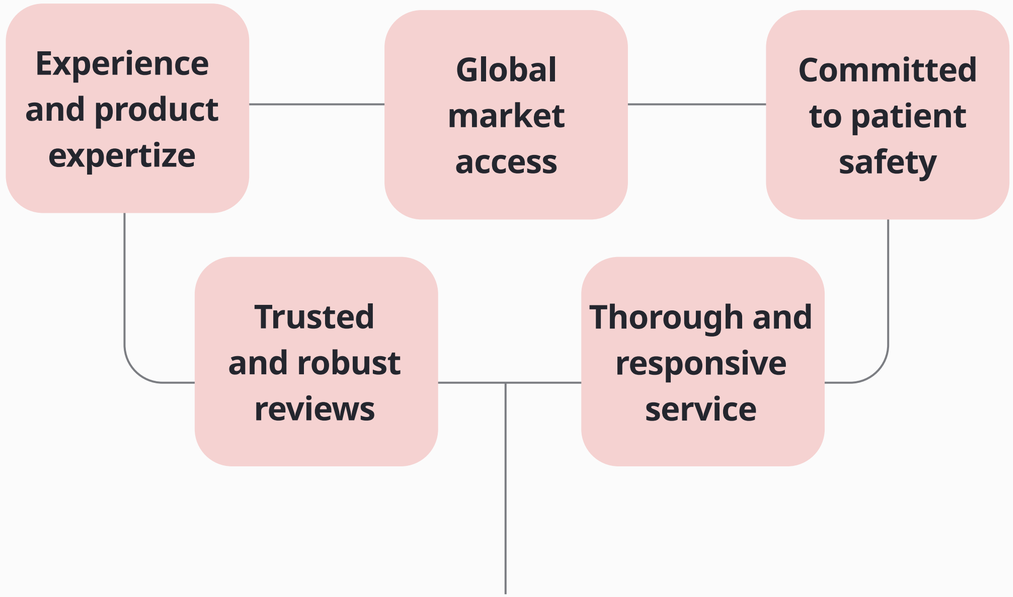
Why choose BSI



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 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.

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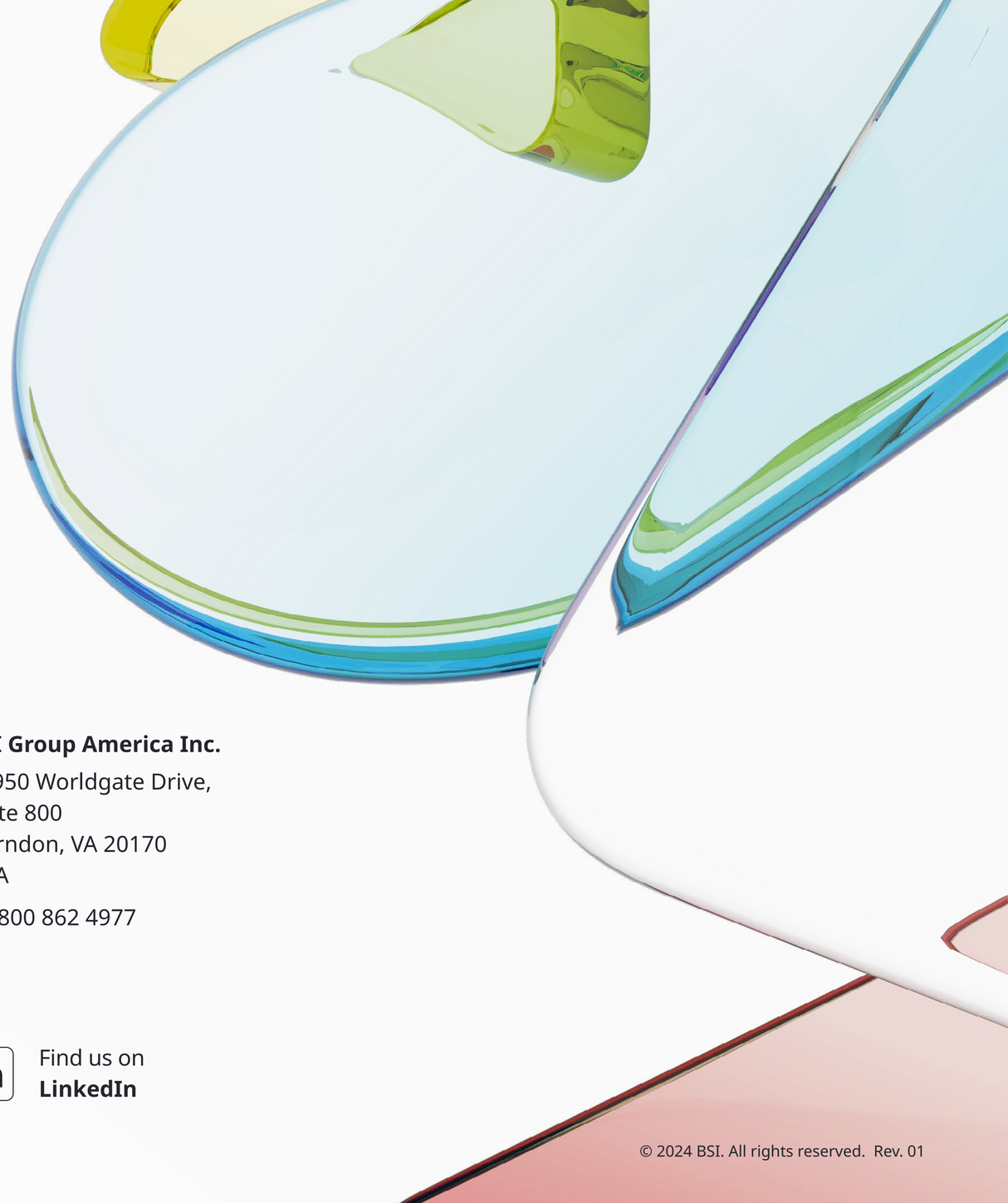
Your partner in progress



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