bsi.

...making excellence a habit.™

CE-Excellence

The most efficient routes to market

Technical documentation reviews for CE Marking

European market access with a trusted Notified Body.

BSI is a leading EU Notified Body; we review technical documentation as part of a conformity assessment to ensure that medical devices meet the necessary safety and performance requirements to allow them to be placed on the market.

The BSI team has a unique set of expertise from our product and regulatory experience that allows us to provide a rigorous review of your technical documentation. This gives confidence in your certification to you and your key stakeholders.

BSI offers technical documentation review through our CE-Excellence services; you will be assigned a dedicated Scheme Manager to work with you throughout your product certification journey and will remain your point of contact thereafter.

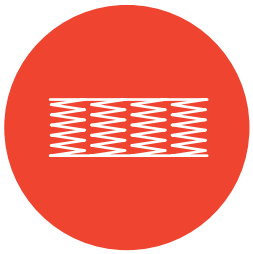
BSI has a strong commitment to providing the most experienced and efficient routes to market. This is why we offer you CE-Excellence, our trusted review services.

Orthopaedic

Dental

Active Implantable Devices

Active Devices



Vascular

IVDs

General Devices

Biological Substances

Drug-Devices Combination

Don't delay...

excellence

Accessing the European market brings challenges that can lead to delays in your product launch. Such delays can be costly for the manufacturer, and for patients who require care. However, there are stringent requirements in place to ensure patient and user safety, as well as the performance of the device.

Maintaining quality, delivering excellence

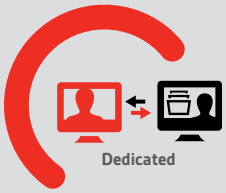
Our CE-Excellence services are designed for medical device manufacturers wanting to get their products to European markets efficiently and safely. They combine efficiency with the integrity, independence, and robustness you have come to expect from BSI.

Explore the services in more detail.

CE-Excellence has three service options

CE-Standard

The CE-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.



CE-Dedicated FastTrack

The CE-Dedicated FastTrack review service allows you to book your technical documentation review in advance. The service is conducted remotely with your BSI Product Expert, who uses the time allocated to your company to conduct a focused review of your technical documentation. This allows you to interact with your BSI expert, providing them information during the review. The CE-Dedicated FastTrack service improves the efficiency of the process, and provides predictability in your planning of the review.

CE-Onsite FastTrack

The CE-Onsite FastTrack review service is conducted at your premises; a BSI Product Expert visits the facility for a period of time. CE-Onsite FastTrack reviews allow for dynamic communications and opportunities for immediate responses to questions raised by the reviewer. Planning a CE-Onsite FastTrack review in advance provides you with more predictability and the reassurance of knowing when your BSI Product Expert will be at your premises.

Note:
Our services do not guarantee a CE Marking certificate will be issued within a certain amount of working days, but are based on completing the review process with either a positive or negative recommendation. CE-Dedicated FastTrack and CE-Onsite FastTrack are not available for devices utilizing animal tissue, blood derivatives or medicinal substances.

Global market access

BSI has a range of market access services to meet your regulatory needs. Our experts have experience with and knowledge of the regulatory requirements of many global markets, making us a trusted Certification Body worldwide.

BSI's role in global market access:

- European Notified Body for CE Marking
- ISO 13485 Quality Management Systems Auditor
- Medical Device Single Auditing Program (MDSAP) Auditing Organization in Australia, Brazil, Canada, Japan and USA
- Brazilian INMETRO 60601 Auditor
- Hong Kong Conformity Assessment Body
- Japanese PMD Act Registered Certification Body
- Malaysian Conformity Assessment Body
- Taiwanese Technical Cooperation Partner

BSI offer a comprehensive range of medical device training courses covering a variety of formats, including public or if you prefer to have a group of employees attend a course together, choose inhouse – it's your choice. Courses can be customised to your requirements.

CE marking training courses:

- Introduction to CE Marking Training Course
- Medical Devices CE Marking Training Course
- Introduction to CE Marking for the In Vitro Diagnostics Directive
- Application of the In Vitro Diagnostic Directive Training Course

Talk to BSI

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