



## CE-Dedicated Benefits:

Speed-to-Market Benefits with Same High Quality Reviews

Reviews Completed in 45 Working Days

Dedicated Time Period with BSI Product Experts

CE Marking for Class III Medical Devices

Customized and Flexible Review Scheduling

No Traveling to Customer Site Required

Patients Gain Faster Access to New Medical Technology

*BSI is a Notified Body and Registrar governed by the highest of standards to ensure effectiveness, safety and independence.*

## Accelerate Your Global Medical Device Launches with BSI CE-Dedicated FastTrack

BSI CE-Dedicated FastTrack Program is designed for Medical Device Manufacturers needing to get their products to European markets quickly and safely. This premium CE Marking Program is for high risk medical devices requiring design dossier reviews. We provide you the same high quality reviews just at an accelerated rate, usually within 45 working days or less.

### How it Works

Our experienced and knowledgeable BSI Product Experts dedicate a specific period of time committed solely to working with you and your team to complete the review. The steps include:

- Evaluate if FastTrack is a good fit for the product and the company
- Conduct Customer needs analysis
- Estimate number of Dedicated review days and schedule
- Perform pre-review preparation meeting to organize resources
- Conduct CE-Dedicated Review
- Discuss next steps and process review as necessary

Our commitment is to complete the review with either a positive or negative recommendation. However in the majority of cases the entire process is completed in 45 working days or less.

### How Can We Achieve Accelerated Reviews?

The key to accelerating the review process is in creating a dynamic and rapid information interchange. BSI employs a variety of communication technologies, paperless submissions and our expertise to bring you a technically advanced environment. Combined with the customer's strong motivation to get their product to market, excellent documentation and being responsive to questions creates optimum conditions to accelerate your global medical device launches.

### Patient Benefits

Patients and medical professionals continue to advance their knowledge of new medical technologies. This often results in increase demand for better outcomes. Gaining faster access to new medical devices can benefit the patients as well as all who are involved in the healthcare delivery system.

### Flexible Review Scheduling

CE-Dedicated is conducted via telecommunications, as a result it does not require Product Experts to travel to the customer's site. This means scheduling times can be more flexible and adjusted if needed.



## Dedicated BSI Product Experts Dedicated To You

### Contact us:

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www.bsiamerica.com

### BSI Speed-to-Market Programs

Our Speed-to-Market CE Marking Programs are designed for Medical Devices needing Design Dossier reviews for European markets.

#### CE-90 Standard

Setting a new level of service in the industry with our standard program in which most reviews are completed within 90 working days.

#### CE-45 FastTrack

This is an expedited service in which reviews are usually completed within 45 working days from submission.

#### CE-Dedicated FastTrack

BSI Experts set an exclusive interval of time, utilizing telecommunications to conduct the review. It aims to complete the review in 45 working days.

#### CE-Onsite FastTrack

Our Product Experts visit the client's site for a specific time period to conduct dynamic "real-time" reviews with a goal of completion in 45 working days.

### Related Services

- ISO 13485 Quality Management
- CE Marking
- Health Canada CMDCAS
- Japan PAL
- FDA Third-Party Programs
- Medical Device Training
- Standards
- Environmental Management
- Business Continuity Management
- Product Testing
- Information Security

Programs do not guarantee a CE Marking certificate in a certain amount of working days but commits to completing the review process with either a positive or negative recommendation. Programs exclude reviews outside BSI's control (e.g., products containing medicines, animal or blood derivatives).

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### BSI Healthcare

BSI Healthcare is a well respected, world-class Notified Body and Registrar dedicated to providing robust regulatory and quality management reviews and product certifications for medical device manufacturers.

**Product Expertise** – our professional, knowledgeable and responsive Team of Experts include product specialists, engineers, clinicians, microbiologists, quality and regulatory affairs experts that have in-depth understanding of medical device technologies.

**Global Access** – we have more than 100 years of experience and operate in over 100 countries with offices around the world to serve you.

**Speed-to-Market** – providing flexible solutions for medical device manufacturers needing accelerated pathways to global markets.

**Confidence** – Clients around the globe trust us to deliver value, confident in our professionalism, ability to provide reviews that will stand up to scrutiny within predictable timelines.

**Partnership** – Establishing a long-term partnership with each client is a vital part of the BSI philosophy. We focus on open communications throughout the review while helping manufacturers understand the process needed to place compliant products on global markets.

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