Flexible, FastTrack solutions from BSI

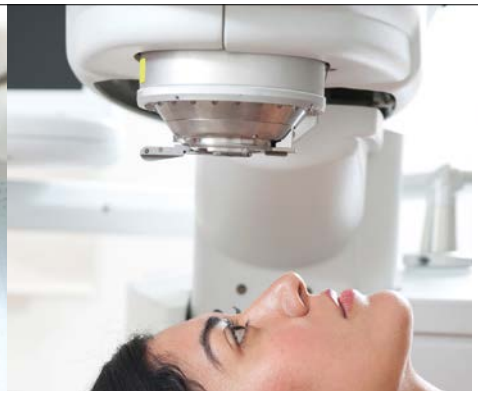
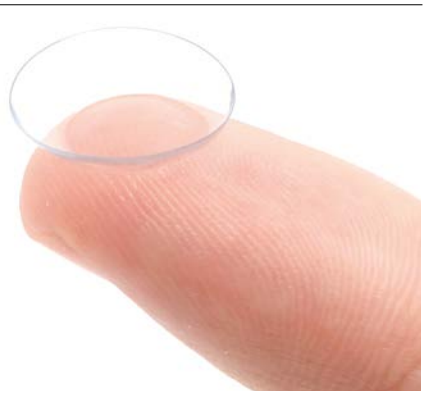
An Ophthalmic Medical Device Notified Body

Expertise and experience

Giving clarity to compliance

bsi.

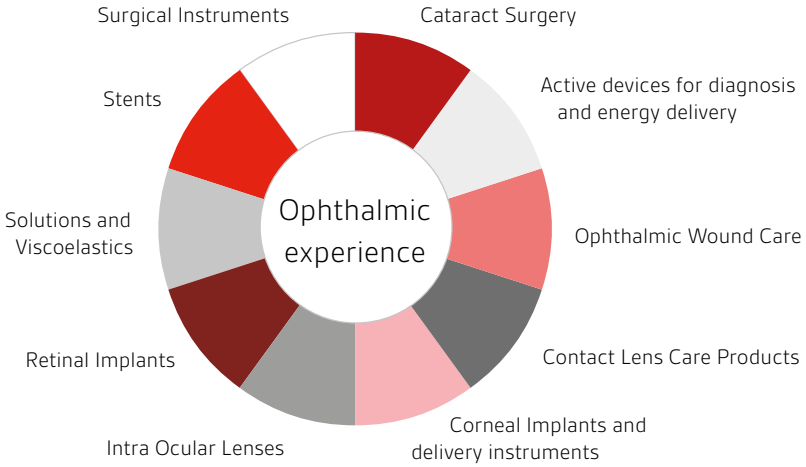
...making excellence a habit.™

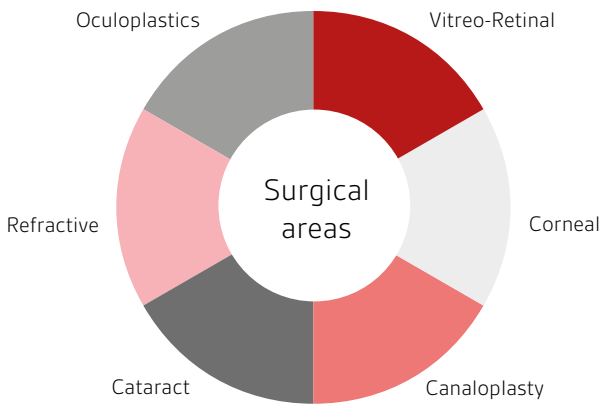
Unrivalled expertise from the premier Ophthalmic Notified Body.

BSI is proud of the technical expertise we can provide in Ophthalmics. Our team has experience gained from both industry and regulatory roles. We have direct experience with manufacturers working with a wide range of ophthalmic medical devices.

BSI's Ophthalmic experience includes a wide range of devices including:



Covering the following surgical areas...



Three unique reasons to make BSI your Ophthalmic Notified Body

Experience and expertise:
You can be rest assured by increased patient safety, thereby reducing your corporate risk.

Bespoke service:
BSI offers a premium customized service, giving you a greater level of flexibility as well as predictability.

Market Access:
Our speed-to-market service means your product reviews won't slow down your launch plans, helping you to stay ahead of the competition.

Fast and experienced routes into global markets – giving clarity to compliance

Be prepared

In the competitive medical device market place, ensuring that product development meets all regulatory requirements is essential. Understanding and consideration of the complicated clinical and regulatory requirements early in the product lifecycle could ensure your company gains the competitive advantage. Consolidated clinical and regulatory planning will assist your company to maximise resources and minimise time to market.

CE marking: Speed-to-market

Clients work with us because we understand the challenges medical device manufacturers face in getting compliant products to market quickly.

CE-90 Standard: Our standard service, is completed within 90 days from submission, giving you predictability for accurate planning.

CE- FastTrack: Our FastTrack programmes deliver the speed-to-market you need to be competitive and move ahead of the competition. The aim is review completion in 45 days from submission with a choice of options:

- CE-45 Standard: 45 day service
- CE-Onsite: The review service is conducted at your premises, allowing for a faster time-line and dynamic communication.
- CE-Dedicated: Your review will be conducted remotely, your Product Expert will be able to arrange flexible schedules with you.

Worldwide access

Our partnership approach offers a wide range of proven regulatory and quality management programmes that work together for full international compliance. Our QMS solutions include: ISO 13485, ISO 9001, ISO 14001 and many more.

BSI partner with international regulators to help you get your products approved in the USA, Canada, Japan, Australia, Hong Kong, Russia and Taiwan.

Seamless transfer to BSI

If you decide to transfer your certification to BSI, we can offer a seamless exercise with comprehensive support and the absolute minimum level of disruption. With expertise encompassing the full range of industry sectors and management system standards.

Certification support

Throughout the certification process and beyond we can continually help you by providing:

- Expert training courses:
  - In-house for your company
  - Public courses, see website for the latest schedule
  - On-line, we have an increasing number of short courses running via distance learning
- Regulatory Updates, helping you plan for the future
- Free webinars
- Access to relevant standards

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Please Note: our programmes do not guarantee 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.

FastTrack and CE-90 are not available for devices utilizing animal tissue or containing human blood derivatives or medicinal substances.

Global expertise

Certification services

ISO 13485 QMS Auditing

CE marking

Health Canada CMDCAS

Japan PAL

FDA 510k Third-Party Review Programme

FDA Accredited Persons Inspections

Australia EU CAB

Hong Kong CAB

Russian Registration Certification

Taiwan TCP

Training courses

CE marking for AIMD, MDD and IVD

ISO 13485 QMS

Medical Devices Risk Management ISO 14971

CE marking Medical Devices with Software

Compiling and Maintaining Technical Files and Design Dossiers

Clinical Evaluation for Medical Devices

Device - Drug Combinations: Practical Guidance on Borderline Issues and the Consultation Process

Process Validation for the Medical Device industry

Post Market Surveillance and Vigilance

Medical Devices Utilizing Material of Animal Origin.

Your partner in worldwide compliance: Call BSI today on +44 845 080 9000 or visit medicaldevices.bsigroup.com – to start your partnership

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