Flexible, FastTrack solutions from BSI

A Woundcare Medical Device Notified Body

Expertise and experience

Aiding the healing process

Updated February 2016

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Unrivalled expertise from the premier woundcare Notified Body

Woundcare is a diverse field with a wide range of treatments, utilizing a vast array of technologies. Devices can span the entire spectrum of classification. The diversity of intended uses and technologies means that an expert CE marking Notified Body is essential.

BSI is designated with a full scope which includes woundcare devices utilizing tissue of animal origin including TSE risk species.

For woundcare devices which incorporate ancillary medicinal substances, BSI has a proven track record of successful consultations with many competent authorities and the European Medicines Agency (EMA).

Our woundcare team has a wealth of experience gained from both the device and pharmaceutical industries, to understand the complete range of woundcare technologies.

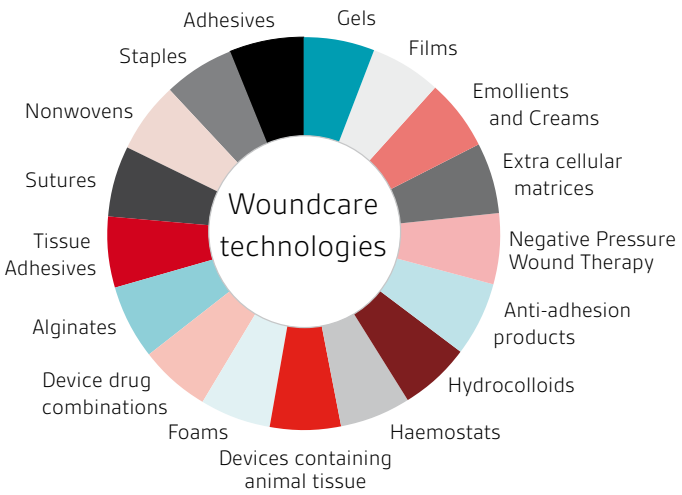
Three unique reasons to make BSI your woundcare Notified Body

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

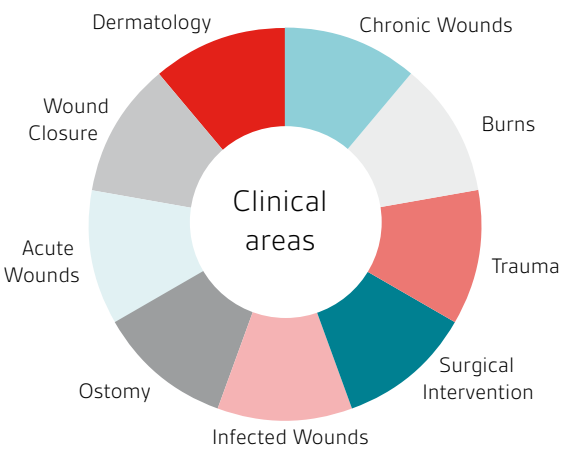
Bespoke service:
BSI can offer a premium customized service, giving you a greater level of flexibility as well as predictability.

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.

BSI's woundcare technologies includes:



Covering the following clinical areas...



Fast routes into global markets with the guidance and experience of BSI.

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 reviews are completed within 90 days from submission, giving you predictability for better 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 timeline 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 expertise 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 works with international regulators to ensure we understand what is required to get products approved in the USA, Canada, Japan, Australia, Brazil, Hong Kong, Malaysia 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

Thoughout the certification process and beyond we can continually support you. We can provide:

- Expert training courses:
  - In-house for your company
  - Public courses, see website for the latest schedule
- Regulatory Updates, helping you plan for the future
- Free webinars
- Access to relevant standards.

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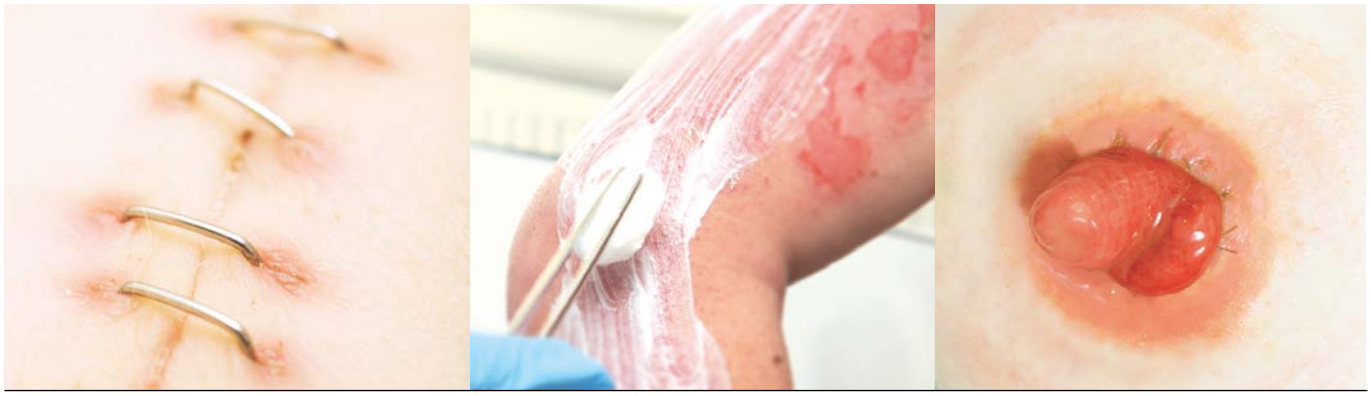
Please Note: our programmes do not guarantee CE marking certificate will be issued within a certain amount of working days, but are based on completing the review process with either a positive or negative recommendation.

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



Global expertise

Certification services

CE marking

ISO 13485 QMS Auditing

Health Canada CMDCAS

Japan PMD Act

MDSAP Auditing – Australia, Brazil, Canada, Japan and USA

Brazil INMETRO 60601 auditing and combined INMETRO, ISO 13485 and CE marking auditing

Hong Kong CAB

Malaysia CAB

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.

Global Market Access Courses

Your partner in worldwide compliance: Call BSI today on 1 800 862 6752 or visit bsigroup.ca/medical– to start your partnership

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Toronto Office
6205B Airport Road, Suite 414
Mississauga, ON L4V 1E3
T: 416 620 9991
TF: 1 800 862 6752
F: 416 620 9911

Ottawa Office
515 Legget Drive, Suite 110
Ottawa, ON K2K 3G4
T: 613 271 7007 TF: 1 800 862 6752 F: 613 271 9007

Montréal
1, Place Ville Marie, Suite 2901
Montréal, QC H3B 2C4
T: 514 940 1778
TF: 1 800 862 6752
F: 514 866 2115

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