

Certification for medical devices

Your partner in European compliance

raising standards worldwide™





Fast and experienced route to global markets

Product Specialties

BSI specializes in multifaceted, high-risk medical devices requiring Design Dossier Reviews. BSI's core competency and our advanced level of skill are perfectly matched to handle the complexities of these types of medical devices which include:

- Vascular
- Orthopedic
- Active Implantable
- Electro-Medical
- Sterilization Validation
- Human Blood and Animal Tissue
- Novel Technologies
- Invasive and Surgical
- Wound Care
- Dental
- Combination / Medicinal Substances
- Ophthalmic



BSI is a respected, world-class Notified Body dedicated to providing rigorous regulatory and quality management reviews and product certifications for medical device manufacturers – around the world.

For more than 100 years, BSI's expertise has provided an assurance of safety and quality to manufacturers in over 100 countries.

The challenges medical device manufacturers face in today's highly competitive marketplace make it essential to ensure that your product meets all regulatory and quality requirements before launch. It is critical to work with a leader who understands the industry and has the experience to review and confirm the products' readiness for market – efficiently, reliably and promptly. BSI is such a company that has been leading the way in assisting manufacturers to navigate through the maze of regulatory requirements. In the race to get new medical devices to market, speed is a crucial component.

BSI has a strong commitment to providing the most experienced and fastest routes to global markets. This adds up to the kind of speed-to-market you need if you want to stay competitive, or more importantly, move ahead of the competition.

CE-90 Standard

Our clients enjoy working with us because we understand the challenges medical device manufacturers face in getting compliant products on the market quickly. We are continually developing Speed-to-Market Programmes to meet the demands of the medical device industry—such as our CE-90 Programme.

The CE-90 is our standard Design Dossier service in which most reviews are completed within 90 working days from submission. We give you more predictability for better results.

CE-45 FastTrack

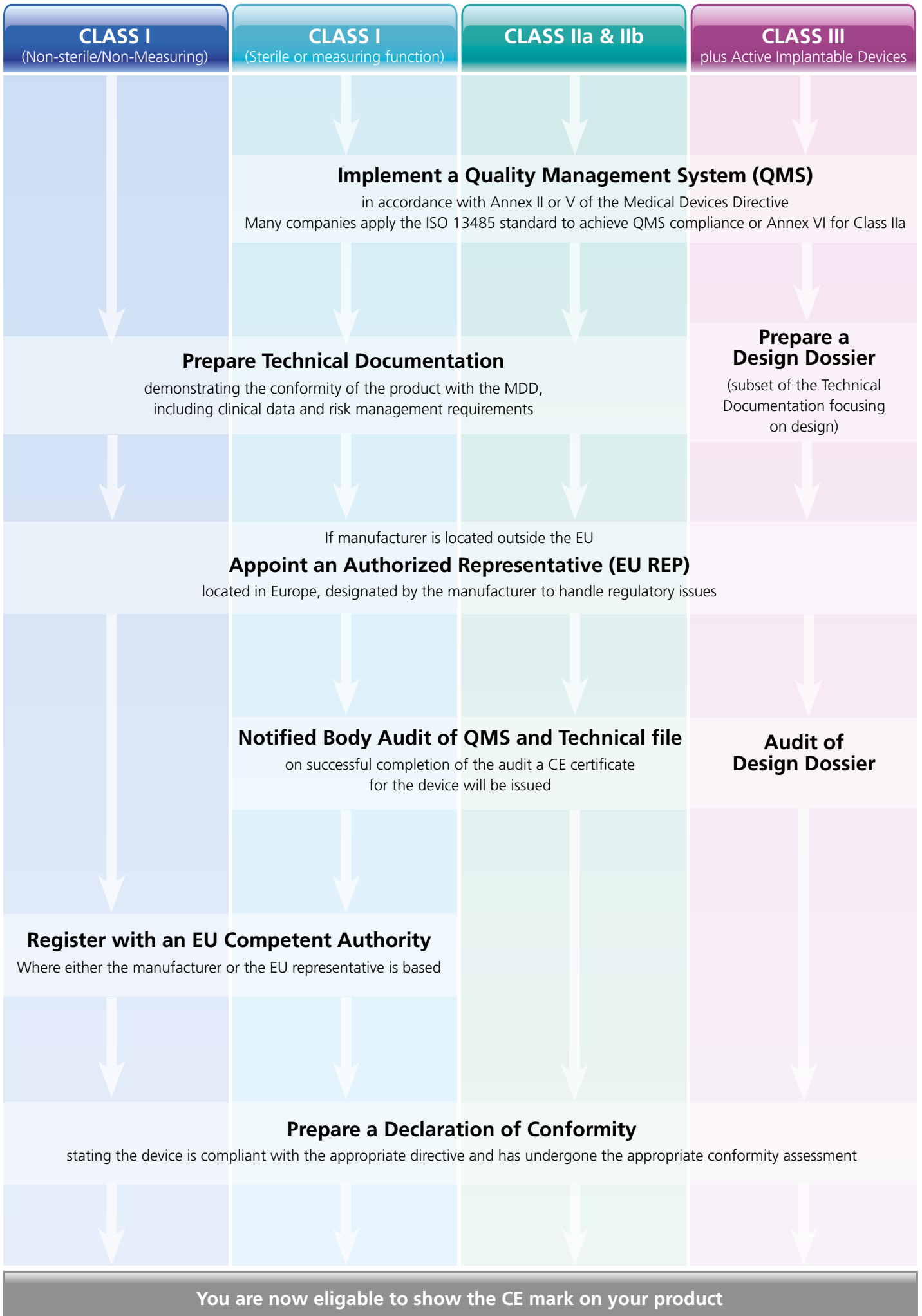
We make getting your product to global markets as important to us as it is to you. BSI knows every day can have an impact on the bottom line, so we created the CE-45 FastTrack Programme.

The CE-45 is an expedited Design Dossier service where most reviews are completed within 45 working days from submission. Our goal is to assist you in getting your products to market faster, realising a faster return on your investment.

Onsite FastTrack

Onsite FastTrack Review Service is conducted at the customer's premises, in which BSI Product Experts visit the facility for a dedicated period of time.

This expedited service works toward a CE Marking target of 45 working days from submission. Onsite Reviews usually allow for a much faster timeline with dynamic communications and opportunities for immediate response to questions. Real time for real results.



Product certification worldwide

When choosing BSI you can rely on our five core values:

Product Expertise – our diverse and experienced team brings in-depth knowledge and understanding of complex medical device technologies.

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

Speed-to-Market – providing flexible solutions for manufacturers needing accelerated pathways to global markets

Confidence – our stringent review process combines speed with experience, integrity, independence and predictability.

Partnership – we focus on establishing a partnership with each client so we can work together to meet their goals.

Our one-stop shop approach offers a wide range of proven regulatory and quality management programmes that work together for full international compliance.

These include:

CE marking

FDA 510k Third -Party Review Program

Australia – EU CAB

Pre-Clinical Trial Review

Japan PAL

Hong Kong Conformity Assessment Body (CAB)

Health Canada CMDCAS

Your partner in Worldwide compliance: call BSI today on +44(0)8450 765608 or visit www.bsigroup.com/healthcare – to start your partnership

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