

99% of course attendees would strongly recommend BSI Training



Why choose BSI for your training?

- **World-leading industry subject matter experts**, over 200 BSI Medical Device product and regulation experts.
- **Course instructors are active practitioners in their subjects**, ensuring the latest developments are fully understood.
- **State of the art courses**, representing up-to-date thinking on the current and possible future interpretations of the directives, standards and guidance.
- **Accelerated learning philosophy** – you don't just sit and listen, you experience the subject. You participate in hands-on exercises, case studies, group work, mock real life situations and learning aids including photos, charts, games and quizzes.
- **On-line, Public or In-house Course** – its your choice. We schedule public courses for you to book onto or if you prefer to have a group of employees attend a course together, choose in-house. Courses can be customised to your requirements.
- **Cost efficient** – A BSI training course can provide you with the knowledge to save significant time and money in bringing your product to market.
- **Make excellence a habit** – BSI training will prepare you to take the excellence habit back to your business.

bsi.

...making excellence a habit.™

Medical Device Training Courses.

BSI Medical Device Training:

Helping to make regulatory compliance excellent.

● **CE marking**

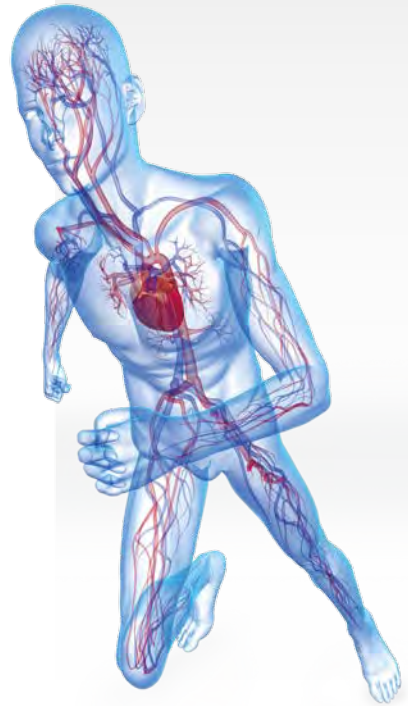
- Introduction to CE marking
- Medical Device CE marking
- Introduction to CE marking for the In Vitro Diagnostics Directive
- Application of the In Vitro Diagnostics Directive.

● **ISO 13485**

- Introduction to ISO 13485
- Implementing ISO 13485
- Internal Auditor ISO 13485
- Lead Auditor ISO 13485 (non-certified, IRCA, TPECS).

● **Specialisms**

- 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 Utilising Material of Animal Origin.



Visit [medicaldevices.bsigroup.com](https://www.medicaldevices.bsigroup.com) or email eu.medicaldevices@bsigroup.com to book your course.