# BSI Transitions

## Medical Devices Regulation

## BSI Training Academy

# Medical Devices Directive to Regulation Transition training course

### Essential information about the course

The Medical Devices Regulation (EU 2017/745) has replaced the Medical Devices Directive (93/42/EEC) as the legislation detailing the requirements that manufacturers have to meet to place medical devices on the market in the European Union.

This long awaited text brings with it more scrutiny of technical documentation, including clinical evaluation and post-market clinical follow-up, and traceability of devices through the supply chain.

Our one day training course has been designed to introduce medical device manufacturers and other economic operators in the supply chain to the key changes to requirements for CE marking following the publication of the new Medical Devices Regulation (MDR).

Our expert tutors will make sure you complete the course feeling confident that you can apply the knowledge as soon as you step back inside your organization.

The course is structured to optimize your learning using our unique approach to accelerated learning. It will consist of a blend of practical activities, group discussions and classroom learning.

**Please note: This course will not cover In Vitro Diagnostic Devices. This course does not focus on mapping the Active Implantable Medical Devices (AIMD) to the MDR, however, the course will provide value to AIMD clients by looking at the new Regulation and how to transition to the MDR.**

### Our course agenda

**This training course will cover:**

- Welcome, introductions and benefits to you
- Course aim, learning objectives and course structure
- Changes in the structure and administration of the Regulation
- New economic operators affected by the Regulation
- Scope of the MDR
- Risk classification
- Select Conformity Assessment Procedure
- Identify applicable Safety and Performance Requirements (SPR)
- Assemble technical documentation
- Apply Conformity Assessment Procedure
- Assign Unique Device Identification (UDI)
- Complete Declaration of Conformity
- Affix CE mark
- Post-market surveillance and vigilance
- Transition arrangements as stipulated within the Regulation
- Reflection, feedback and close of the day

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...making excellence a habit.™

# **Medical Devices Directive to Regulation Transition** training course

We want to make sure you have the best learning experience possible. That's why we offer a range of training courses from beginner to expert. We create a positive learning environment so you retain the knowledge and acquire skills that will continue to be of use beyond the course.

**Make sure this is the right course for you.**

### This is the course for you if you are:

- A medical device manufacturer, especially if your role is in:
  - Regulatory Affairs
  - Design and Development
  - Clinical Affairs Specialists
  - Quality Management
  - Quality Assurance
- An Authorised Representative
- An economic operator, including importers and distributors
- A Consultant

### What is the course like?

- One day
- Led by a BSI expert tutor
- Relaxed and comfortable learning environment
- You'll receive detailed course notes to take away

You should have a good understanding of the existing Medical Devices Directive (93/42/EEC) or the Active Implantable Medical Devices Directive (90/385/EEC).

### How will I benefit?

- Understand the key changes in the transition from the MDD to the new MDR
- Communicate the impact to your organization of the key changes introduced by the MDR, and the transition arrangements defined within the MDR
- Identify the next steps for your organization to meet the MDR requirements

## Why invest in training from BSI?

BSI training courses are delivered by experts with experience in the subject. They're truly passionate about sharing their knowledge and ensuring you learn. Trusted experts with years of hands-on and business experience, they bring the subject matter to life with relevant and contemporary examples.

Upon successful completion of your course, you'll receive an internationally recognized BSI certificate.

### Training delivered at your site

This could be a convenient and cost effective option, especially if you have multiple delegates. **Talk to one of our experts to find out more.**

### Next steps with the BSI Academy

Want to learn more? You may be interested in:

**ISO 13485 Transition courses**

**MDSAP: Fundamentals and Readiness**



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Find out more.

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