Sterling ACADEMY

Build the competence. Prove it with confidence.

COURSE BROCHURE

AWARENESS TRAINING · MEDICAL DEVICE QUALITY

EU MDR Awareness (Regulation (EU) 2017/745)

Self-paced online training (video) · 11 modules · about 115 min of video · about 3 hours in total · English, with captions

Understand the EU Medical Device Regulation, Regulation (EU) 2017/745: who it applies to, how devices are classified and certified, and what manufacturers and other economic operators must do.

WHO IT IS FOR

Staff of medical device manufacturers, importers, distributors and authorised representatives, quality, regulatory, R&D, sales and supply-chain teams, and managers preparing to place devices on the EU market.

WHAT YOU WILL LEARN

- Explain the purpose and scope of the EU MDR and the roles of economic operators
- Describe how devices are classified and which conformity assessment routes apply
- Recognise the general safety and performance requirements and technical documentation
- Explain clinical evaluation, UDI and the role of EUDAMED
- Describe post-market surveillance, vigilance and the person responsible for regulatory compliance
- Understand the transitional provisions and how to follow changes to the Regulation

MODULES (11)

1. The EU MDR at a glance
2. Scope, definitions and non-medical products
3. Manufacturers, importers and distributors
4. Classification
5. Conformity assessment and CE marking
6. Safety and performance, technical documentation
7. Clinical evaluation and the QMS
8. UDI, EUDAMED and registration
9. Post-market surveillance, vigilance and the PRRC
10. In vitro diagnostic devices: the IVDR
11. Transition, enforcement, changes and the exam

PRICE

US$19 per learner

Per learner, by team size

1–10 learners	**US$19**
11–50 learners	**US$15**
51–200 learners	**US$13**

Excluding taxes.

DURATION

About 3 hours in total (117 minutes of video)

MODULES

11

FORMAT

Self-paced online training (video)

LANGUAGE

English, with captions

ACCESS

12 months

CERTIFICATE

Sterling Academy Certificate of Completion

Scan for the course page, prices and enrolment