

REF. E-MDR-MOD-02 - E-LEARNING

EUROPEAN REGULATIONS

COURSE DESCRIPTION

The Obligations of Economic Operators module presents the parties who are governed by Regulation (EU) 2017/745 and the obligations incumbent on economic operators active on the Medical Device (MD) market

DURATION

37 minutes, including a 25-minute lesson and 12 minutes of guizzes

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TECHNICAL PREREQUISITES Computer and internet connection

METHODS USED

The module is composed of a lesson in the form of an interactive video with voice-off and learning activities. The module can be accessed 24/7. Reminders are sent to monitor knowledge acquisition and avoid a break in the learning curve.

TARGET TRAINEES

All individuals involved in the MD sector

PREREQUISITES

Knowledge of the Regulation's main definitions and general principles (N.B. covered in the Overview module)

ACCESS

The CEISO ACADEMY platform can be accessed for a period of two months within two business days at most of approval of your order.

ADDITIONAL BENEFITS

Summary presentation of the regulation

Support materials designed by experienced consultants-trainers

Interactive lesson

Short modules that can be accessed as often as required and autonomously

As an option, you may select Q&A sessions with one of our consultants-trainers

EDUCATIONAL GOALS

 Become familiar with the economic operators on the medical device market

Obligations of Economic

Operators

Regulation (EU) 2017/745

Identify the obligations incumbent on each of these operators .

COURSE CONTENT

Assistance with navigation/Module objectives/Presentation of the course content

- 1. Parties involved
- 2. Manufacturer's obligations
- 3. Authorized representative's obligations
- 4. Importer's obligations
- 5. Distributor's obligations

EVALUATION METHODS

Course evaluation guiz Satisfaction survey Attendance certificate

This training is assessed based on each individual's acquisition of knowledge via a quiz at the end of the program (success criteria >= 80%). If trainees pass the quiz, they receive their training certificate, as well as the corrected quiz, by email.



Do you have a question? Contact us! Email: formation@ceiso.fr Tel.: +33 6 42 58 94 52

