



# General Safety and Performance Requirements

## Regulation (EU) 2017/745

REF. E-MDR-MOD-07 – E-LEARNING

EUROPEAN REGULATIONS

### COURSE DESCRIPTION

The General Safety and Performance Requirements (GSPR) module presents the safety and performance, design and manufacturing requirements and the information that must be provided with a Medical Device (MD).

### DURATION

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



### E-LEARNING

### 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.

### EDUCATIONAL GOALS

- Become familiar with the safety and performance requirements set out in Annex I of the Regulation
- Differentiate the general requirements from those regarding performance, design and manufacturing
- Be aware of the information to be provided with an MD

### COURSE CONTENT

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

1. General requirements
2. Performance, design and manufacturing requirements
3. Requirements relative to information provided with the device

### 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

### EVALUATION METHODS

Course evaluation quiz  
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!

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