MDSSPRO

TRAINING CATALOGUE 2026

Harts Farm Way, Havant PO9 1HS
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Registered company: 10492707

EO STERILIZATION: COMPLIANCE TO ISO 11135

Course Description

This course is designed to provide participants with understanding of the EN ISO 11135 requirements for sterile medical devices and compliance with MDR and MDD.
This 1 day training provides an in-depth knowledge of the EN ISO 11135 requirements and study cases.

Learning objectives

On completion of this training, participants will be able to:

- Identify the links between MDD/ MDR and EN ISO 11135
- Define the requirements for the validation of sterilisation
- Define the type of indicator used and its compliance with ISO 11138-1 and -2
- Define the requirements for the sterilisation in routine and the release of batches
- Identify the content of a validation report of sterilisation

Intended audience

- Regulatory, quality assurance managers and personnel
- Design and development managers and personnel
- Quality control personnel
- Students who would like to work in the medical device field

Course duration

1 day

Prerequisites

Participants should have basic knowledge of microbiology and packaging requirements.

EO STERILIZATION: COMPLIANCE TO ISO 11135

How will I learn?

We use interactive learning techniques, keeping the course varied and with applications and study case. Our tutors are the best and will make sure your learning needs are met. Choose between online or in-company courses tailored to your business.

Who are we

We are a dedicated organization to training for medical device companies with tutors who have practical experience with the type of device involved and who are transferring knowledge to your organization.

Content of the course

I- Introduction

II- Design of the device's material and interaction with the sterilising agent
   a. Choice of the material for the medical device
   b. Choice of the packaging

III- What type of indicator to use
   a. Chemical
   b. Biological indicator

IV- Validation: IQ, OQ, PQ
   a. IQ
   b. OQ
   c. PQ

V- Requalification
   a. Criteria
   b. Methodology

VI- Impact of the medical device's modification on sterilisation process and extension of range
   a. Definition of the product family
   b. Methodology

VII- Release of sterile products in routine
   a. Based on bioindicator

b. Parametric release
c. Example

VIII- Biocompatibility aspects: EO residual
a. Limits defined by the standard
b. Methodology
c. Example

IX- Microbiological aspects: Bioburden and sterility testing
a. Methodology of bioburden testing
b. Example
c. Methodology of sterility testing

Price

We are providing online training course for £500 per person on our platform https://mdsspro.talentlms.com/index. The content is available for 3 months after registration.
A certificate is delivered after completion of the training.
On site training is tailored by on your needs. For more details contact info@mdsspro.com

Next dates for 2026

28th May 2026
22nd July 2026
29th September 2026
25th November 2026

STEAM STERILISATION: COMPLIANCE TO EN ISO 17665

Course Description

This course is designed to provide participants with understanding of the EN ISO 17665 requirements for sterile medical devices and compliance with MDR 2017/415.
This training provides an in-depth knowledge of the EN ISO 17665 requirements and study cases.

Learning objectives

On completion of this training, participants will be able to:

- Identify the links between MDR 2017/745 and EN ISO 17665
- To understand the requirements from ISO 11737-1 bioburden and ISO 11737-2 for sterility testing
- Define the requirements for the validation of sterilisation
- Define the type of indicator used and its compliance with ISO 11138-1 and -3
- Define the requirements for the sterilisation in routine and the release of batches
- Identify the completeness and compliance of a validation report of sterilisation to EN ISO 17665

Intended audience

- Regulatory, quality assurance managers and personnel
- Design and development managers and personnel
- Quality control personnel

Course duration

1 day

Prerequisites

Participants should have basic knowledge of microbiology and packaging requirements.

STEAM STERILISATION: COMPLIANCE TO EN ISO 17665

How will I learn?

We use interactive learning techniques, keeping the course varied and with applications and study case. Our tutors have a long experience and will make sure your learning needs are met. Choose between online or in-company courses tailored to your business.

Who are we

We are a dedicated organization to training for medical device companies. Our tutors have practical experience with the type of device involved and who are transferring knowledge to your organization using a pragmatic approach.

Content of the training

I- Introduction
- Regulatory environment
- Description of gamma, e-beam and X-ray methods
- Type of microorganism
- Resistance of microorganisms to sterilisation process

II- Characterisation of the device's material
- Choice of sterilisation method during design of the product
- Type of packaging
- Compatible packaging with the sterilisation process

III- What type of indicator to use
- Different type of indicators: chemical and biological
- Compliance to ISO 11138-1 and -3

IV- Validation- IQ-OQ-PQ
- Operations during IQ
- Operations during OQ
- Description of the tests during OQ
- Documentation of OQ validation
- Tests during PQ
- Methods
- Documentation

V- Requalification operations during the year

STEAM STERILISATION: COMPLIANCE TO EN ISO 17665

- Tests to do

VI- Controls in routine

- Tests to do

VII- How to handle failed cycle

VIII- Quality of water for the steam

IX- Impact of the medical device's modification on sterilisation process and extension of range

- Changes to product or process
- Family adoption

X- Bioburden and sterility testing

- Validation of the method
- Monitoring in routine

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Next dates for 2026

04th June 2026
12th August 2026
09h October 2026
03rd December 2026

Course Description

This course is designed to provide participants with understanding of the EN ISO 11137-1 requirements for sterile medical devices and compliance with MDR 2017/745.
This training provides an in-depth knowledge of the EN ISO 11137-1 and AAMI TIR 35 requirements and study cases.

Learning objectives

On completion of this training, participants will be able to:

- Identify the links between ISO 13485, FDA 21 CRF820, MDR and EN ISO 11137-1, -2, -3
- To understand the requirements from ISO 11737-1 bioburden and ISO 11737-2 for sterility testing
- Define the requirements for the validation of sterilisation
- Define the type of dosimeters used and its compliance with ISO ASTM 52628
- Define the requirements for the sterilisation in routine and the release of batches
- Identify the completeness and compliance of a validation report of sterilisation to EN ISO 11137-1.

Intended audience

- Regulatory, quality assurance managers and personnel
- Design and development managers and personnel
- Quality control personnel

Course duration

1 day

Prerequisites

Participants should have basic knowledge of microbiology and packaging requirements.

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Who are we

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Content of the course

I- Introduction, presentation of the regulatory environment MDR 2017/745, FDA21 CFR Part 820 and ISO 13485
- Regulatory environment
- Description of gamma, e-beam and X-ray methods
- Type of microorganism
- Resistance of microorganisms to sterilisation process

II- Characterisation of the device's material and interaction with the irradiation
- Choice of sterilisation method during design of the product
- Type of packaging
- Compatible packaging with the sterilisation process

III- What type of dosimeter to use
- Different type of indicators: chemical and biological
- Compliance to ASTM 52628

IV- Validation- IQ

V- Validation- OQ & dose mapping
- Requirements for each method of sterilisation
- Aspects affecting the dose distribution
- Dose mapping
- Documentation

VI- Validation- PQ
- Methods used for establishing the dose: VDmax 15, VDmax25 and Method 1 and 2
- Dose mapping and place of the dosimeters
- Documentation

VII- Requalification- Controls in routine

- Dose audit

VIII- Impact of the medical device's modification on sterilisation process and extension of range

- Changes to product or process
- Family adoption

IX- Bioburden and sterility testing

- Validation of the method
- Monitoring in routine

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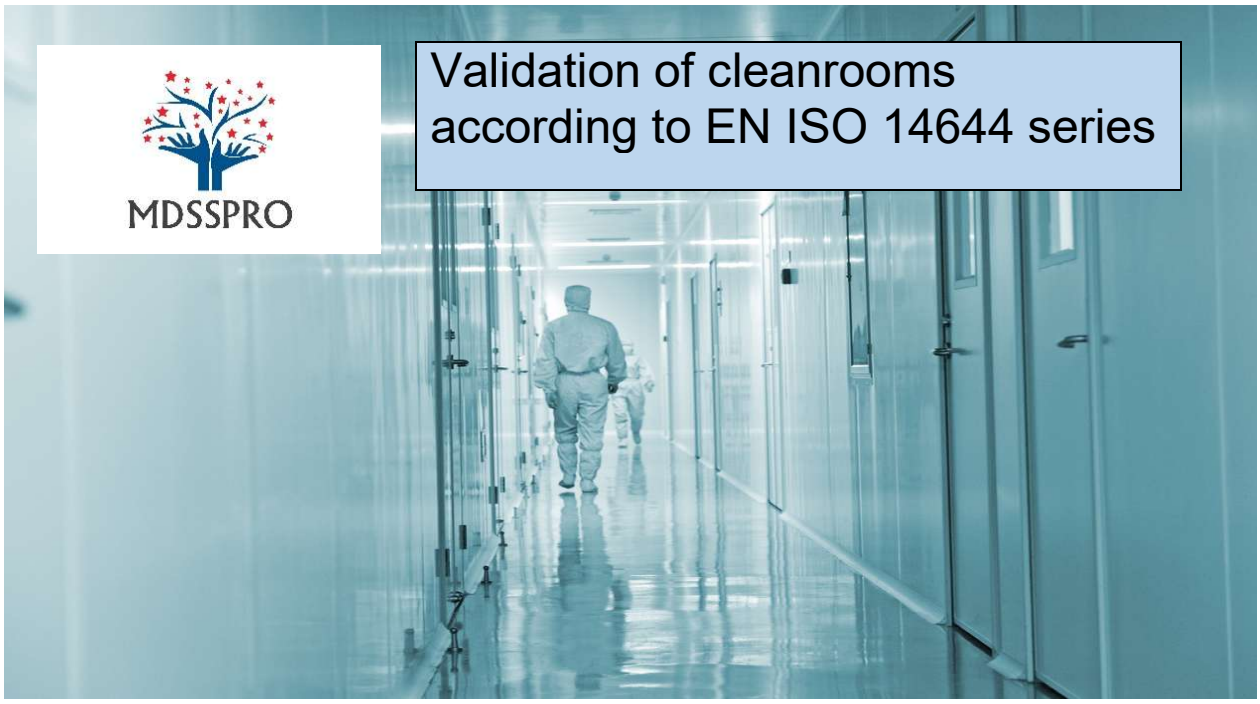
Next dates for 2026

14th May 2026
07th September 2026
03rd November 2026



Validation of cleanrooms according to EN ISO 14644 series

MDSSPRO

Description of the training

This course is designed to provide participants with understanding of the EN ISO 14644 series requirements for sterile medical devices and compliance with UK MDR 2002 and EU MDR 2017/745.
This 1-day training provides an in-depth knowledge of the EN ISO 14644-1 to -5 requirements and study cases.

Learning objectives

On completion of this training, participants will be able to:

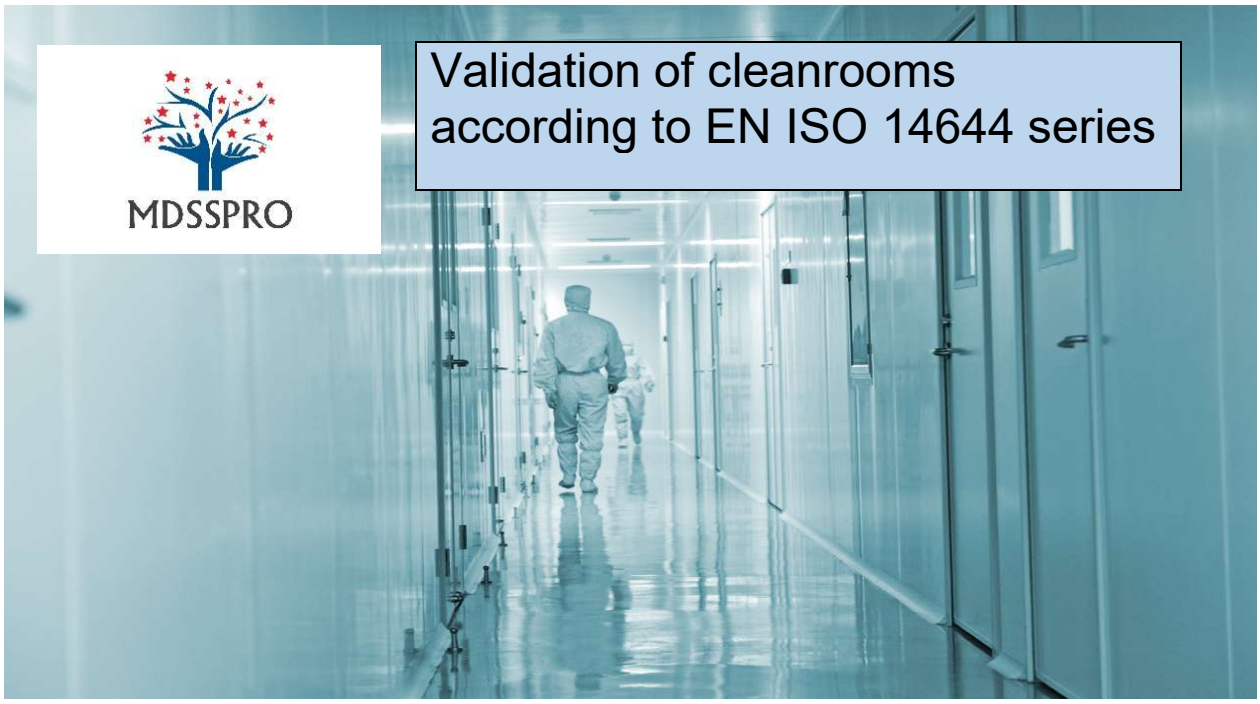
- Identify the links between UK MDR 2002/EU MDR 2017/745 and ISO 14644 series
- Explain terms and definitions
- Explain how fulfilling the requirements ensure a low bioburden
- Define the cleanroom requirements
- Identify the appropriate methodology used for monitoring
- Define the key information of the validation of the cleanroom

Intended audience

- Regulatory, quality assurance managers and personnel
- Design and development managers and personnel
- Quality control personnel

Prerequisites

Participants should have basic knowledge of microbiology, physics and quality management systems.



Validation of cleanrooms according to EN ISO 14644 series

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Who we are

We are a dedicated organization to training for medical device companies with tutors who have practical experience with the type of device involved and who are transferring knowledge to your organization

Content of the training

I- Introduction
   a) History and regulation
   b) Type of cleanrooms

II- II- Classification of the cleanroom
   a) Particle classification
   b) Writing the report

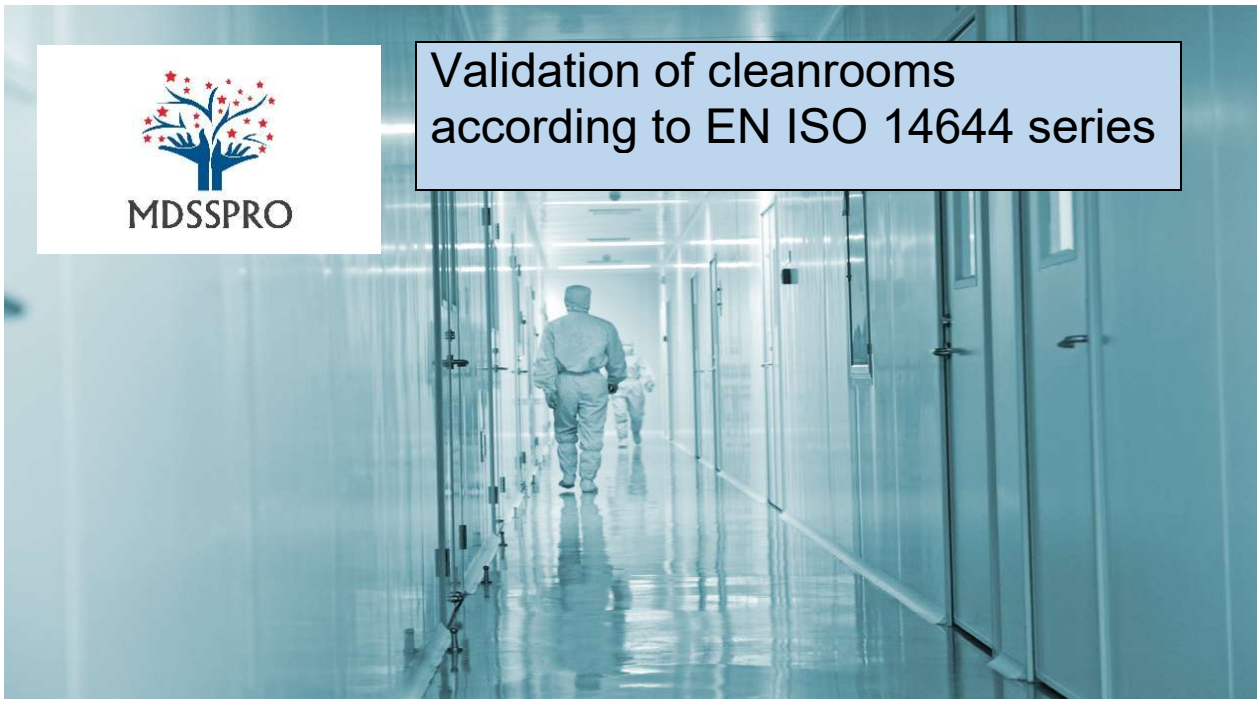
III- III- Control of contamination
   a) Source of contamination
   b) How to reduce contamination

IV- V- Setting up a cleanroom
   a) Project definition
   b) Example
   c) Type of constructions
   d) Report
   e) Maintenance

V- VI- Validation of the cleanroom

VI- VII- Monitoring of the cleanroom
   a) What to measure and how to measure it
   b) Records
   c) Monitoring plan

VII- VIII- Maintenance of the cleanroom
   a) Requirements
   b) Techniques



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Next dates for 2026

25th June 2026
28th August 2026
26th October 2026

Course description

This 1-day training course gives participants an in-depth knowledge of IEC 62304 requirements and its application.

It guides organisations through the regulatory requirements for:

- embedded software for active medical devices
- standalone software for medical devices

It focuses on MDR and MDD compliance and explains how businesses can guarantee safety claims of medical devices.

Learning objectives / course outcomes

By the end of the course, participants will be able to:

- Identify the links between MDD/ MDR and IEC 62304
- Explain how the requirements relate to the product lifecycle
- Define the software requirements
- Define the classification of the software
- Define the key documents of the risk management file
- Define the key deliverables for software validation

Who is the course suitable for?

- Regulatory quality managers and personnel
- Design and development managers and personnel

Course outline

I- Introduction
II- Classification
III- Risk management requirements
IV- Software development plan
V- Software requirements - specifications
VI- Architecture
VII- Software - detailed specifications
VIII- Verification, integration and testing
IX- Maintenance
X- Configuration management
XI- Software problems - resolution

Prerequisites

Participants should have a basic knowledge of ISO 14971 and quality management systems.

What format does the training take?

MDSSPRO uses interactive teaching techniques, keeping the course varied and stimulating through exercises, working applications and case studies. Experienced and knowledgeable industry-leading tutors ensure individuals stay engaged throughout the course and that the learning objectives are met.

The course can be run online or onsite at company offices.

MDSSPRO's online training course is powered through a Performant Software platform. Online tutors are available throughout the length of the course offering full support to course participants, answering questions, offering advice and explaining course material as required.

About MDSSPRO

MDSSPRO specialises in helping companies understand, manage and implement MDR. Its high-quality courses are run by experienced tutors adept at transferring knowledge and understanding.

Price

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Next dates for 2026

12th June 2026
02nd September 2026
20th November 2026

Course description

This 1-day training course gives participants an in-depth knowledge of EN ISO 14971 requirements and its application.

It guides organisations through the regulatory requirements all type of devices, active or non-active sterile devices.

It is making the link with MDR and MDD requirements and explains how businesses can guarantee safety claims of medical devices.

Learning objectives / course outcomes

By the end of the course, participants will be able to:

- Identify the links between MDD/ MDR and EN ISO 14971
- Explain how the requirements relate to the product lifecycle
- Define the risk management requirements
- Define the key documents of the risk management file
- Define the key deliverables for risk management documentation

Who is the course suitable for?

- Regulatory quality managers and personnel
- Design and development managers and personnel

Course outline

I- Introduction
   a. Objectives of the course
   b. Structure
   c. Introduction and international context of application
   d. Quick test

II- Risk management plan
   a. Requirements
   b. How to write a risk management plan
   c. Application to medical device (study case)

III- Risk analysis- FMEA
   a. Requirements
   b. How to identify the hazards

c. What type of FMEA to do
d. Application to medical device (study case)

IV- Risk management report
a. Requirements
b. How to write a risk management report
c. Application to medical device (study case)

V- Conclusion
a. Content of a risk management file
b. Skills learned
c. Test

Prerequisites

Participants should have a basic knowledge of:

- quality management systems

and/or

- the medical device industry

What format does the training take?

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A certificate is delivered after completion of the training.

On-site training is tailored by your needs. For more details contact info@mdsspro.com