

# LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

## ISO 11135 — Sterilization of Health-Care Products Ethylene Oxide

*ISO Certification Programme*



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### LAPT — London Academy of Professional Training

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**Reference** HL-EQP-11135 • ISO Health

UKPRN 10067351 • Registered in England and Wales, company 4984798

AT A GLANCE

|               |                                                |
|---------------|------------------------------------------------|
| REFERENCE     | HL-EQP-11135                                   |
| AWARD         | Certificate                                    |
| ASSESSMENT    | 430 marks — 258 to pass (60%)                  |
| PREREQUISITES | None                                           |
| VALIDITY      | Lifetime                                       |
| AWARDING BODY | LAPT — London Academy of Professional Training |

CURRICULUM

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| <div><div>1</div><div>Ethylene Oxide Sterilization Principles</div><div>5 chapters · 30 classes 85 marks</div></div> <div><div><div>• 1 Introduction to Ethylene Oxide Sterilization Fundamentals — 6 classes</div><div><div>› 1.1 Define Ethylene Oxide and its Role in Sterilization</div><div>› 1.2 Explain the Mechanism of Action of Ethylene Oxide on Microorganisms</div><div>› 1.3 Identify the Key Advantages of Using Ethylene Oxide for Sterilization</div><div>› 1.4 Discuss the Health and Safety Considerations of Ethylene Oxide Usage</div><div>› 1.5 Outline the Regulatory Standards Governing Ethylene Oxide Sterilization</div><div>› 1.6 Apply Ethylene Oxide Sterilization Principles to Case Studies</div></div></div><div><div>• 2 ISO 11135 Standards and Regulatory Framework — 6 classes</div><div><div>› 2.1 Understand ISO 11135 Standard Overview</div><div>› 2.2 Explore the Regulatory Framework for Ethylene Oxide Sterilization</div><div>› 2.3 Identify Key Terminology in Ethylene Oxide Sterilization</div><div>› 2.4 Examine the Principles of Ethylene Oxide as a Sterilant</div><div>› 2.5 Analyze Compliance Requirements for ISO 11135 Certification</div><div>› 2.6 Apply ISO 11135 Standards to Real-World Sterilization Scenarios</div></div></div><div><div>• 3 Ethylene Oxide Sterilization Process and Equipment — 6 classes</div><div><div>› 3.1 Explain the Fundamentals of Ethylene Oxide Sterilization</div><div>› 3.2 Identify the Key Components of Ethylene Oxide Sterilization Equipment</div><div>› 3.3 Describe the Ethylene Oxide Sterilization Cycle Phases</div><div>› 3.4 Analyze Factors Influencing Ethylene Oxide Sterilization Efficacy</div><div>› 3.5 Demonstrate Proper Techniques for Loading Sterilization Chambers</div><div>› 3.6 Evaluate Safety Protocols and Environmental Considerations in Ethylene Oxide Use</div></div></div><div><div>• 4 Validation and Monitoring of Sterilization Processes — 6 classes</div><div><div>› 4.1 Define Key Concepts of Sterilization Validation</div><div>› 4.2 Identify the Stages of Ethylene Oxide Sterilization Process</div><div>› 4.3 Explain the Importance of Monitoring Sterilization Parameters</div><div>› 4.4 Demonstrate Validation Techniques for Ethylene Oxide Systems</div><div>› 4.5 Analyze Data from Sterilization Cycle Reports</div><div>› 4.6 Apply Corrective Actions Based on Monitoring Results</div></div></div><div><div>• 5 Risk Management and Safety Measures in Ethylene Oxide Use — 6 classes</div><div><div>› 5.1 Assessing Risks in Ethylene Oxide Sterilization Processes</div><div>› 5.2 Identifying Safety Hazards Associated with Ethylene Oxide</div><div>› 5.3 Implementing Control Measures for Ethylene Oxide Safety</div><div>› 5.4 Developing Emergency Response Plans for Ethylene Oxide Exposure</div><div>› 5.5 Evaluating Effectiveness of Safety Protocols in Ethylene Oxide Use</div><div>› 5.6 Training Staff on Risk Management and Safety for Ethylene Oxide Operations</div></div></div></div> |
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**• 1 Understanding ISO 11135: Fundamentals of Ethylene Oxide Sterilization** — 6 classes

- › 1.1 Explore the Fundamentals of ISO 11135
- › 1.2 Identify Key Benefits of Ethylene Oxide Sterilization
- › 1.3 Understand the Ethylene Oxide Sterilization Process
- › 1.4 Discuss Safety Considerations and Risks Related to Ethylene Oxide
- › 1.5 Evaluate Compliance Standards in Ethylene Oxide Sterilization
- › 1.6 Apply ISO 11135 Standards to Real-world Scenarios

**• 2 Regulatory Framework: Compliance Requirements for Health-Care Products** — 6 classes

- › 2.1 Understand Regulatory Frameworks for Health-Care Products
- › 2.2 Identify Key Standards for Sterilization Processes
- › 2.3 Analyze the Role of ISO 11135 in Compliance
- › 2.4 Evaluate Risk Management Strategies for Ethylene Oxide Sterilization
- › 2.5 Implement Documentation Practices for Regulatory Compliance
- › 2.6 Assess Continuous Improvement in Sterilization Practices

**• 3 Quality Management Systems: Integration with ISO 11135** — 6 classes

- › 3.1 Understand Key Principles of ISO 11135 for Effective Quality Management
- › 3.2 Analyze the Relationship Between ISO 11135 and Regulatory Compliance
- › 3.3 Identify Essential Components of Quality Management Systems in Healthcare
- › 3.4 Evaluate the Role of Risk Management in ISO 11135 Implementation
- › 3.5 Develop Strategies for Integrating ISO 11135 into Existing Quality Systems
- › 3.6 Assess the Impact of Ethylene Oxide Sterilization on Product Quality and Safety

**• 4 Risk Management in Ethylene Oxide Sterilization: A Deep Dive** — 6 classes

- › 4.1 Identify key risks in Ethylene Oxide sterilization processes
- › 4.2 Analyze regulatory requirements for Ethylene Oxide sterilization
- › 4.3 Evaluate risk assessment methodologies for healthcare sterilization
- › 4.4 Develop a risk management plan for Ethylene Oxide sterilization
- › 4.5 Implement monitoring strategies to mitigate risks in sterilization
- › 4.6 Review case studies on risk management failures in sterilization

**• 5 Audit and Continuous Improvement: Ensuring Ongoing Compliance** — 6 classes

- › 5.1 Understand the Basics of ISO 11135 Standards
- › 5.2 Identify Key Audit Requirements for Sterilization Processes
- › 5.3 Develop Effective Audit Checklists for Compliance
- › 5.4 Analyze Audit Findings for Continuous Improvement
- › 5.5 Implement Corrective Actions Following Audit Reviews
- › 5.6 Establish a Culture of Continuous Compliance Monitoring