LAPT

LONDON ACADEMY OF PROFESSIONAL TRAINING

CERTIFICATE

ISO 11607 — Packaging for Terminally Sterilized Medical Devices

ISO Certification Programme

LAPT — London Academy of Professional Training

Address 85 Great Portland Street, W1W 7LT, London, United Kingdom

Email info@lapt.org

Telephone +44 7513 283044

Web lapt.org

Reference HL-EQP-11607 • ISO Health

UKPRN 10067351 • Registered in England and Wales, company 4984798

6	10	60	430	60%	Lifetime
SUBJECTS	CHAPTERS	CLASSES	TOTAL MARKS	PASS MARK	VALIDITY

AT A GLANCE

REFERENCE	**HL-EQP-11607**
AWARD	**Certificate**
ASSESSMENT	**430 marks — 258 to pass (60%)**
PREREQUISITES	**None**
VALIDITY	**Lifetime**
AWARDING BODY	**LAPT — London Academy of Professional Training**

CURRICULUM

1 ISO 11607 Regulations

5 chapters · 30 classes **85 marks**

• 1 Fundamentals of ISO 11607: Understanding Regulatory Frameworks — 6 classes

- › 1.1 Explore the Importance of ISO 11607 in Medical Device Packaging
- › 1.2 Identify Key Components of the ISO 11607 Regulatory Framework
- › 1.3 Analyze the Relationship Between ISO 11607 and International Standards
- › 1.4 Compare ISO 11607 with Other Regulatory Requirements
- › 1.5 Assess the Impact of Compliance on Medical Device Safety and Efficacy
- › 1.6 Implement Best Practices for Adhering to ISO 11607 Standards

• 2 Packaging Design Requirements for Terminally Sterilized Medical Devices — 6 classes

- › 2.1 Identify Key Packaging Design Principles for Medical Devices
- › 2.2 Analyze Material Selection Criteria for Sterile Packaging
- › 2.3 Evaluate Barrier Properties Essential for Packaging Integrity
- › 2.4 Assess the Role of Packaging Design in Sterilization Processes
- › 2.5 Implement Compliance Verification Strategies for Packaging Designs
- › 2.6 Develop a Packaging Design Plan Aligned with ISO 11607 Standards

• 3 Validation of Packaging Processes for Sterility Assurance — 6 classes

- › 3.1 Outline the Importance of Validation in Packaging Processes
- › 3.2 Identify Key Standards and Regulations in ISO 11607
- › 3.3 Describe the Packaging Process for Terminally Sterilized Medical Devices
- › 3.4 Explain the Principles of Sterility Assurance in Packaging
- › 3.5 Apply Validation Techniques for Packaging Processes
- › 3.6 Assess Compliance through Documentation and Review

• 4 Risk Management in Packaging for Terminally Sterilized Devices — 6 classes

- › 4.1 Identify Key Risks in Packaging for Terminally Sterilized Devices
- › 4.2 Analyze the Impact of Packaging Risks on Sterilization Outcomes
- › 4.3 Develop Risk Mitigation Strategies for Packaging Design
- › 4.4 Implement Risk Control Measures in Packaging Processes
- › 4.5 Evaluate the Effectiveness of Risk Management Practices
- › 4.6 Communicate Risk Management Findings to Stakeholders

• 5 Quality Control and Assurance in ISO 11607 Compliance — 6 classes

- › 5.1 Explore Key Components of Quality Control in ISO 11607
- › 5.2 Analyze Risk Management Practices Relevant to Quality Assurance
- › 5.3 Examine the Role of Validation in Packaging Processes
- › 5.4 Assess Compliance with Testing Requirements in ISO 11607
- › 5.5 Implement Best Practices for Quality Control Documentation
- › 5.6 Develop a Continuous Improvement Plan for Quality Assurance

2 Materials Science in Packaging

0 chapters **65 marks**

3 Packaging Design Principles

5 chapters · 30 classes **85 marks**

- **1 Fundamentals of Packaging Design for Medical Devices** — 6 classes
  - 1.1 Identify Key Principles of Medical Device Packaging Design
  - 1.2 Analyze the Importance of Sterilization in Packaging
  - 1.3 Explore Materials Used in Medical Device Packaging
  - 1.4 Assess Design Considerations for User Safety and Compliance
  - 1.5 Evaluate Packaging Integrity and Performance Testing Methods
  - 1.6 Apply ISO 11607 Standards to Real-world Packaging Scenarios
- **2 Materials Selection for Sterile Packaging** — 6 classes
  - 2.1 Identify Key Materials for Sterile Packaging
  - 2.2 Analyze Material Properties for Sterilization Compatibility
  - 2.3 Evaluate Performance Criteria in Packaging Design
  - 2.4 Integrate Regulatory Requirements in Material Selection
  - 2.5 Compare Biodegradable Options for Sustainable Packaging
  - 2.6 Develop a Material Selection Strategy for Medical Devices
- **3 Design Considerations for Sterilization Methods** — 6 classes
  - 3.1 Identify Key Sterilization Methods for Medical Device Packaging
  - 3.2 Analyze Material Properties Impacting Sterilization Efficacy
  - 3.3 Evaluate Packaging Configuration for Compatibility with Sterilization
  - 3.4 Apply Design Principles for Preventing Sterilization Contamination
  - 3.5 Develop Strategies for Validating Packaging Integrity Post-Sterilization
  - 3.6 Create a Risk Assessment for Packaging Design During Sterilization Processes
- **4 Testing and Validation of Packaging Systems** — 6 classes
  - 4.1 Identify Key Standards for Testing Packaging Systems
  - 4.2 Analyze Methods for Validation of Packaging for Sterilized Devices
  - 4.3 Evaluate Environmental Impact on Packaging Integrity
  - 4.4 Conduct Performance Testing of Packaging Materials
  - 4.5 Interpret Test Results and Validate Packaging Efficacy
  - 4.6 Develop a Compliance Strategy for Continuous Improvement
- **5 Compliance and Quality Control in Packaging Design** — 6 classes
  - 5.1 Analyze Regulatory Standards for Packaging Compliance
  - 5.2 Examine Quality Control Processes in Packaging Design
  - 5.3 Identify Key Factors in Material Selection for Medical Packaging
  - 5.4 Evaluate Testing Methods for Sterilization Validation
  - 5.5 Develop a Quality Assurance Plan for Packaging Systems
  - 5.6 Implement Continuous Improvement Strategies in Packaging Quality

4 Project Management for Packaging

0 chapters **65 marks**

5 Quality Assurance Practices

0 chapters **65 marks**

6 Risk Management in Packaging

0 chapters **65 marks**