# ISO 11607 Part 1 and Part 2

# Compliance Requirements

Cathriona O’Neill

Bemis®

# I.S. EN 11607 Introduction

ISO 11607 is the principal guidance document.

Packaging for terminally sterilised medical devices -

Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

Part 2: Validation requirements for Forming, Sealing and Assembly Processes

Part 1 addresses Materials and Design.

Part 2 addresses Packaging Process Validation

Why?

- To satisfy the relevant Essential Requirements of the European Directives
- To obtain CE Mark.
- FDA Recognised Consensus Standard, used for premarket review submissions.



Bemis®

# ISO 11607 Introduction

Definitions / Key Terms:

**Sterile Barrier System (SBS):** The minimum packaging that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use.

**Preformed Sterile Barrier System:** Sterile barrier system that is supplied partially assembled for filling and final closure or sealing e.g. pouches, bags, rigid trays with die-cut lids and open reusable containers.

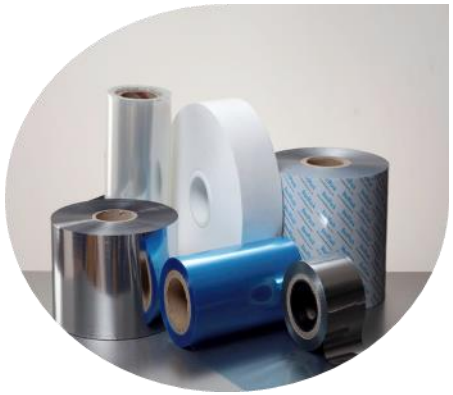
**Protective Packaging:** The configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.

**Packaging System:** The combination of the sterile barrier system and the protective packaging.

# ISO 11607 Introduction

The process for developing a packaging system and the choice of materials must take into account the definitive nature of the device, the intended sterilisation method, the intended use, expiration date, transport and storage.

The combination of the medical device and the packaging system should perform efficiently, safely and adequately in the end-user's hands.





Bemis®

# ISO 11607-1

*Packaging for terminally sterilised medical devices Part 1: Requirements for materials, sterile barrier systems and packaging systems.*



Bemis®

# ISO 11607-1 Overview

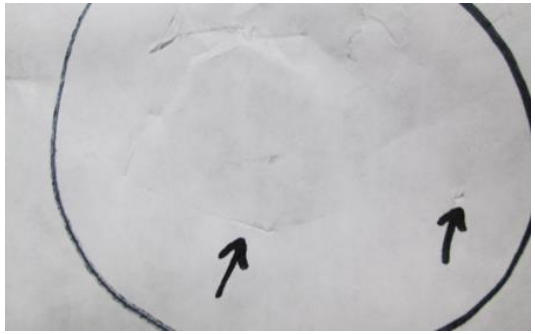
Compliance Assessment to ISO 11607-1 can be used to show compliance with the Essential Requirements of the European Directives concerning medical devices. Applicable to wherever medical devices are placed in sterile barrier systems and sterilised.

Details the elemental attributes demanded of materials and pre-formed systems intended for use in packaging systems.

It takes into consideration the vast array of potential materials, packaging system designs and sterilisation methods. Specifies the requirements and test methods until the point of use.

# ISO 11607-1 General Requirements

- Within a formal quality system.
- Sample Size to be determined.
- Validated Test Methods used.
- When similar devices / same packaging system are used, a rationale for establishing similarities and identifying worst-case configuration to be documented.
- Compliance to be documented.





Bemis®

# ISO 11607-1 General Requirements

**Evidence of the following to be provided:**

Performance / Dynamics Testing

- Conditions of production of the material / SBS established, controlled and recorded.
- Consider how the conditions exposed to effect the physical & chemical characteristics, i.e. holes, thinning, coating and consistency, including normal variation.
- Compatibility with the forming and sealing manufacturing process, i.e. seal type, aseptic presentation, seal strength.
- Biological & Toxicological attributes, cleanliness and non-leaching.

Microbial Barrier

- Air permeance determined by porosity testing. Demonstration of Impermeability satisfies the microbial barrier requirement.
- Reusable containers & tamper-evident seals.

# ISO 11607-1 General Requirements

Compatibility with Sterilisation Process:

- No adverse reaction of material or device.
- Effect of multiple sterilisations.

Labelling system compatibility:

- Not affected by sterilisation, intact, legible, non-transferring.
- Cleaning instructions if re-useable.

Storage, Shelf-Life & Transport:

- Demonstrate that performance characteristics are maintained.

# ISO 11607-1 Design and Development

Consider:

- Customer requirements, number of products per package.
- Sterilisation type, residuals to escape.
- Aseptic presentation.
- Mass and Configuration of the product.
- Sharp edges or protrusions.
- Sensitivity of the product and protection, i.e. environmental limitations, light, moisture, mechanical shock.
- Expiry date limitations of the product.

Design and Development process must be recorded, verified and approved prior to release of the product.

# ISO 11607-1 Packaging-System Performance Testing

- Evaluates the interaction between the packaging and the product in response to the stresses imposed by manufacturing and sterilisation.
- Integrity of the SBS to be demonstrated after sterilisation and transport testing.
- Standardised test methods and the microbial properties of the packaging materials can be used to establish the package integrity and that sterility is maintained.
- Worst case, post 2X sterilisation to be used.
- The ability to provide protection through the hazards of handling, distribution and storage to be assessed.

# ISO 11607-1 Stability Testing

- Integrity of the SBS to be demonstrated over time.
- Data from Accelerated Aging can be used for claimed expiry dates until data from Real Time Aging is available.
- Real Time and Accelerated Aging should begin simultaneously.
- Performed in combination with the device.
- Conditions and duration rationale to be documented.
- If no interaction between the device and the SBS over time is previously determined, previous data can be used.

# ISO 11607-2

*Packaging for terminally sterilised medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.*

# ISO 11607-2 Overview

Specifies the requirements for development and validating of processes for packaging medical devices which are terminally sterilised.
These processes include forming, sealing and assembly of the sterile barrier packaging system.

The development and validation of the packaging processes are crucial to ensure that sterile barrier system integrity is maintained until opened by the users.

This standard is designed to meet the Essential Requirements of the European Medical Device Directives.

# ISO 11607-2 Introduction

Definitions:

**Validation** – documented procedure for obtaining, recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.

**Installation Qualification, IQ** – evidence that equipment is installed and operating properly with its specification.

**Operational Qualification, OQ** – evidence that installed equipment operates within predetermined limits. Produces product or results that meets all specifications.

**Performance Qualification, PQ** – evidence that the equipment as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria. Under Anticipated conditions, the process produces product or results that meets all predetermined specifications.

# ISO 11607-2 General Requirements

Third party certification of a formal quality system is required.

Statistically valid and appropriate Sampling Plans.

TEST METHODS:

- Validated and Suitability documented.
- Acceptance Criteria established.
- Repeatability, Reproducibility and Sensitivity to be determined.

Documentation of compliance may include: Performance Data, Specification and Test Results from Test Methods and from IQ, OQ and PQ.

Validation of existing products may rely on data from previous IQ and OQ. When similar systems are validated, a rationale for establishing similarities and identifying the worst case configuration shall be documented.



Bemis®

# ISO 11607-2 General Requirements

Preformed sterile barrier systems (from Sterile Barrier Manufacturers - SBM's) and sterile barrier system manufacturing process (Medical Device Manufacturers - MDM's own processes) shall be validated.

Include at a minimum an IO, OQ and PQ in this order.

Process Development or Process Design while not formally part of the process validation, should be considered an integral part of forming and sealing. This will identify and evaluate critical parameters, operating ranges, settings and tolerances. Establishes upper and lower processing limits and expected normal operating conditions.

- Process limits should be sufficiently removed from failure or marginal conditions.
- Potential failure modes and action levels having the greatest impact on the process should be identified and addressed via FMEA or Cause and Effect Analysis.
- Essential process parameters such as temp, pressure, dwell time to be evaluated and selected that produce product in control and in specification.



Bemis®

# ISO 11607-2 Validation of Packaging Process

Installation Qualification – IQ
Operational Qualification – OQ
Performance Qualification – PQ

These topics will be detailed in another presentation.



Bemis®

# ISO 11607-2 Packaging System Assembly

The SBS shall be assembled under appropriate conditions to minimize contamination.

Controlled labelling to prevent mislabelling.

Documented procedures for assembly and labelling, including contents, inserts, inner wrapping and absorbent materials, that is based on the validated process assures sterility from a defined sterilisation process.

# ISO 11607-2 Approval & Monitoring

Formal approval of the Process Validation is required.

The documentation shall summarise and reference all protocols, results and state conclusions regarding status of the process.

Procedures shall be established to ensure that the packaging process is under control and within the established parameters during routine operation.

Critical process parameters shall be routinely monitored and documented.

# ISO 11607-2 Revalidation

Documents shall be covered by change-control, verifying and authorizing change.

Processes shall be revalidated if changes which compromise the original validation and affect sterility, safety or efficacy.
Changes that could affect the status of a validated process:

- Changes to the equipment, new equipment installed.
- Changes to the product.
- Raw material changes that impact process parameters.
- The packaging process.
- Transfer of process / equipment to another facility / location.
- Sterilisation-process changes.
- Negative trends in quality or process control indicators.

If the situation does not require that all aspects need to be repeated, the revalidation should reflect this.

Periodic revalidation or reviews should be considered to provide for cumulative effect of multiple minor changes.

# Bemis Laboratory Services

Independent ISO 17025 Accredited Laboratory that can provide:

- Accelerated Aging – range of conditions available.
- Real Time Aging in monitored conditions.
- Range of Transportation Tests, including Drop, Compression, Vibration.
- Packaging Integrity Tests including Seal Strength, Bubble Leak Testing.
- Material Testing including Tensile, Gelbo-Flex, Puncture.
- Analytical Testing of Materials – DSC and FTIR for identification / verification.

# Thank You!