ISO 11607:2006 - focused on:

Sealable Pouches and Reels

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EN ISO 11607 Part 1

Packaging for terminally sterilized medical devices – Requirements for

Materials

Sterile Barrier Systems

Packaging Systems
The new definitions of the ISO Standard

- ISO substitutes the old wording (primary-; secondary-; single-, double-, final-, transportpack):
  Core element of the new concept:

  **Sterile Barrier System**

- The *Sterile Barrier System* is the: 1) *Minimum Package* that 2) *prevents ingress of microorganisms* and 3) *allows aseptic presentation of the product at the point of use*
E.g. sealable pouche: Pictures tell more...

Preformed Sterile Barrier System;
Medical Device MD

MD packed in a sealable pouche...
Pictures tell more...

MD packed in the Sterile Barrier System

Protective Packaging and the Sterile Barrier System
Pictures tell more...

MD packed in the Sterile Barrier System, packed in Protective Packaging = Packaging System
Important new requirement: Validated test methods only!

Special about **validated** test methods:

- Defined high precision
- Determinated reproducibility
- Determinated repeatability

→ Which test methods do apply for seals...?
Validated test method for seals!

Seal strength
Validated test method for seals!

Integrity
Validated test method for seals!

Peel characteristics
Validated test method for seals!

Compatibility with the sterilization process

Steam, 134°C, 5 Min
Some important general requirements...

- The intended applications shall not impair performance or safety and shall not adversely affect the MD

- Materials shall provide a microbial barrier

- Materials shall provide appropriate physical, chemical and biological properties
Requirements for Sterile Barrier Systems:
„Sealable Pouches and Reels”

The seals shall have:

→ Specified seal width
→ Specified seal strength
→ Peel open characteristics for aseptic presentation
→ Microbial barrier (integrity)
EN ISO 11607 part 2

Packaging for terminally sterilized medical devices – Validation requirements for:

- **Forming**,  
- **Assembly**,  
- **Sealing**
The core requirement for sealing

The sealing processes shall be validated:

CSSD

MD Industry
The 3 part validation process

1. Installation qualification (IQ)
2. Operational qualification (OQ)
3. Performance qualification (PQ)
IQ → 1. What’s there!

The complete list of resources:

→ Compliant *Preformed Sterile Barrier Systems*
→ Well trained coworkers
→ State of the art sealing machines with calibrated sensors
→ Clean environmental condition (CSSD)
→ Work- and testmanuals
→ Maintenance and clean procedures
IQ → 2. What‘s critical?

Critical process parameters for the seal process

→ Identification (Temperature...)
→ Control
→ Monitor
→ Warn system with exceed of limits

Find out via testing...
Test of Seal Strength

→ For appropriate test resources...Ask your supplier!
Test of Integrity

Here with simulated 50 micron channel (see →)
Test of Peel Characteristics
And last but not least: Visual Control

Inspection the seals before and after sterilization
OQ → How it works

Process – Frame: Manufacture at upper and lower limits of the critical process parameter(s)

Challenge of the critical process parameter(s): Stops, restarts, continuous run, power offs, etc.:
→ To simulate „real life“
PQ → The result:

1) Consistency: The process will produce compliant *Sterile Barrier Systems* under the specified operating conditions. → Tested

2) Control: The process variables are monitored and recorded. The process is under control
Consequently

Formal approval

Control in routine operation: Monitoring and Documentation of the critical process parameter(s)

Revalidation, if changes are made to the equipment, product, packaging material or process which compromise the original validation.
Finally: Packaging System Assembly

Appropriate conditions, e.g. at the CSSD

Controlled labelling and processing procedures

Validated process to assure sterilization with the defined sterilization process.
Conclusion

The New Standard:

→ reflects packaging and the process of packaging of Medical Devices from a „state of the art“ point of view.
→ corresponds to current regulatory requirements.

Compliance can be achieved very easy by well trained staff working in a clean CSSD using:

→ compliant state of the art Preformed Sterile Barrier Systems: Sealable Pouches and Reels
→ state of the art sealing machines