Importance of sterilization packaging

"every chain is only as strong as its weakest link"

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Because of That….

…the international ISO committee decided to handle the packaging process as an integral part of the instrumental preparation process

ISO / EN Requirements on Packaging & Sealers

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ISO 11607-1:2006

ISO 11607-1:2006 is applicable to industry, to health care facilities, and wherever medical devices are placed in sterile barrier systems and sterilized.

ISO 11607-1:2006 specifies the requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

ISO 11607-2:2006

ISO 11607-2:2006 is applicable to industry, to health care facilities, and wherever medical devices are packaged and sterilized.

ISO 11607-2:2006 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

ISO/TS 16775:2014

ISO/TS 16775:2014 provides guidance for the application of the requirements contained in ISO 11607-1 and ISO 11607-2. It does not add to, or otherwise change, the requirements of ISO 11607-1 and/or ISO 11607-2. It is an informative document, not normative, and does not include requirements to be used as basis of regulatory inspection or certification assessment activities.

EN 868 series

The adoption of the **ISO 11607 series** of standards in Europe in 2006 affected the existing European Standards in the EN 868 series

. EN 868-1:1997 which provided general requirements for packaging materials for sterile medical devices, was withdrawn and replaced by EN ISO 11607-1 in 2006

The remaining EN 868 standards, however, remain and revised editions have been published between 2017 and 2019. This series comprises Parts 2 to 10.

The EN 868 series provides requirements and test methods for a range of specific materials and configurations of sterile barrier systems.

EN868 now comprises the following :

Part 2: Sterilization wrap;

Part 3: Paper for use in the manufacture of paper bags and pouches and reels;

Part 4: Paper bags;

Part 5: Sealable pouches and reels of porous materials and plastic film construction;

Part 6: Paper for low temperature sterilization;

Part 7: Adhesive coated paper for low temperature sterilization processes;

Part 8: Re-usable sterilization containers for steam sterilizers;

Part 9: Uncoated nonwoven materials of polyolefines;

Part 10: Adhesive coated nonwoven materials of polyolefines.

EN 868-5 – European packaging standard

3.1 GENERAL

The purpose of packaging and wrapping of items for sterilization is to provide an effective barrier against sources of potential contamination in order to maintain sterility and to permit aseptic removal of the contents of the pack (see also Section 9).

3.6.2 Heat sealing

Sterilizing bags and flexible packaging materials should be sealed using suitable heat sealing equipment.

When heat sealing packs, checks shall be made to ensure that the seal is complete, especially over the gusset folds of bags or pouches.

Laminated pouch sealing shall conform to AS 1079.4.

NOTE: Appendix F gives information on heat sealing and associated equipment.

EN 868-5 – European packaging standard

Requirements on packaging & sealers

- ✓ effective barrier
- ✓ maintain sterility
- ✓ aspetic presentation
- ✓ suitable heat sealer
- ✓ regular checks of sealed packs
- ✓ routinely monitored

ISO 11607-2 – International validation standard

5 Validation of packaging processes

5.1 General

5.1.1 Preformed sterile barrier systems and sterile barrier system manufacturing processes shall be validated.

Examples of these processes include, but are not limited to:

— rigid and flexible blister forming;

— pouch, reel, or bag forming and sealing;

— form/fill/seal automated processes;

— kit assembly and wrapping;

— assembly of sterile fluid-path products ;

— tray/lid sealing;

— filling and closing of reusable containers;

— sterilization sheets folding and wrapping

5.2.2 Critical process parameters shall be defined.

5.2.3 Critical process parameters shall be controlled and monitored.

5.2.4 Alarms, warning systems, or machine stops shall be challenged in the event that critical process parameters exceed predetermined limits.

5.6 Process control and monitoring

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

5.6.2 Critical process parameters shall be routinely monitored and documented.

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ISO 11607-2:2006 – international validation standard

requirements

- ✓ validatable packaging process
- ✓ critical parameters shall be controlled
- ✓ alarm systems and/or machine stop in case of parameter deviation
- ✓ routine critical parameter monitoring

Summary EN 868-5 and ISO 11607-2

suitable heat sealer

- ✓**critical parameters shall be controlled → ISO 16775**
- ✓ alarm systems and/or machine stop in case of critical parameter deviation
- ✓ validatable

monitoring and checking

- ✓ routine critical parameter monitoring
- ✓ regular checks of sealed packs

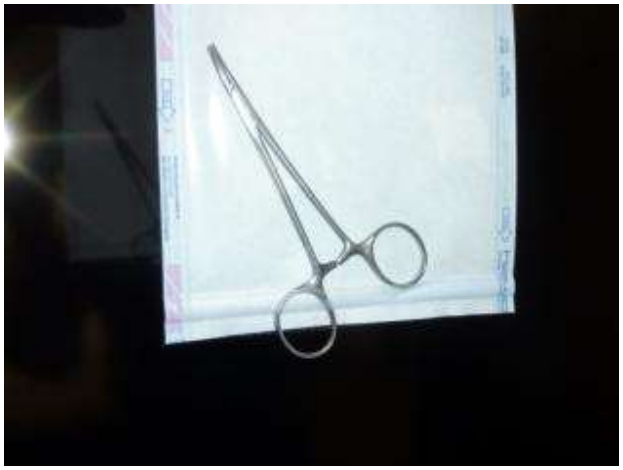
problem 1: unprofessional sealers

simple bar- or pedal sealers are not accaptable in CSSDs or doctor‘s surgeries.

- ✓ sealing line is mostly not wide enough (<6mm)!
- ✓ process doesn‘t run automatically
- ✓ parameters are not under control!
- ✓ parameters cannot be documented

problem 1: unprofessional sealers

As the sealing result is up to the motivation of the user, the packages are either **open** or fusioned!



problem 2: self sealing pouches

A professional study by the University of Tübingen (Germany) found that of 147 professionally closed self seal pouches 47 were leaky (→ Residual Risk of more that 30%)

Summary

Sealing process parameters are (see ISO/TS 16775):
- temperature
- contact pressure

Sealing process parameters have to be monitored and documented

Heat sealing devices must be Validateable

8.6 ROUTINE MONITORING AND CONTROL OF PACKAGING PROCESSES

Packaging procedures shall be performed in accordance with the specification developed during process definition (see Section 6).

Routine monitoring and control of packaging procedures for sterilization wrap, reusable rigid sterilization containers, PSBS and where applicable, self-adhesive PSBS shall ensure that packaged items produced during routine operation meet the specification. This is usually achieved by visually checking each packaged item whilst preparing loads for the sterilizer.

chapter 8.6. Routine Monitoring

Heat sealers used for sealing PSBS or dust covers shall be operated in accordance with the manufacturer's instructions for use. For impulse and rotary heat sealers without a process record, the temperature that the machine has been set for shall be recorded on a daily basis and a visual check shall be made immediately prior to each episode of sealing to ensure that the correct seal temperature has been reached.

For heat sealers where process variables are monitored for each episode of sealing, achievement of correct process variables shall be confirmed at the completion of each episode of sealing (or in accordance with manufacturer's instructions).

On a daily basis, one or more samples of heat-sealed PSBS shall be checked for seal integrity before and after exposure to the sterilization process. This check shall include a visual assessment of seal integrity over the entire length of the seal. See EN 868-5 for further information.

Rigid reusable sterilization containers shall be subject to a visual inspection prior to each use. The visual inspection shall ensure that the container and the lid are free from any dents or cracks, that the seal/gasket is intact along its entire length and is not compressed or pinched, the closure mechanism (handles) lock firmly into position and that the filter (if applicable) has been replaced or is within the acceptable number of reuse cycles.

EN 868-5 is referring to ISO 11607-1 Annex B for seal integrity tests:

Integrity	ASTM F 1929:1998	Standard test method for detecting seal leaks in porous medical packaging by dye penetration
	ASTM F2227: 2002	Standard test method for non-destructive detection of leaks in non-sealed and empty medical packaging trays by CO_2 tracer gas method

Routine Monitoring

ISO 11607-1 Annex B is referring to ASTM F 1929 for seal integrity testing:

→ Leak Test / InkTest

→ InkTests are also available for Tyvek (HDPE) and ULTRA

Alternative: SEAL CHECK

1.seal

2.compare

Alternative: SEAL CHECK

problems can be easily identified with the SEAL CHECK

please make sure that the SEAL CHECK consists of Medical paper (some manufacturers use simple writing paper)

All final product of sterilization packaging are tested for compliance to ISO 11607-1, ISO 11140-1 and EN 868-5 for specific properties listed in below table.

Properties	Unit	Value	Method	Frequency
Seal Width	mm	10±2 mm	EN 868-5 Annex D	For film and paper changes & every 2 hour.
Bubble Test	pcs	No leakage acc. Standard	ASTM F2096-04	Film and paper changed
Pinhole Determination	pcs	No pinhole acc. Standard	EN 868-5 Annex C	Each film roll
Dimension Control	cm	Refer to internal documentation	ASTM F2203-02	Film and paper changed
Leakage Test	pcs	No seal leaks acc. Standard	ASTM F 1929-98	Film and paper changed
Peel Direction	pcs	No fibers on the testing tape	EN 868-5 Annex E	Each printed roll
Steam Indicator Control	pcs	Color change from pink to brown	Visual	Each printed roll
EO Indicator Control	pcs	Color change from green to yellow	Visual	Each incoming material lot
FO Indicator Control	pcs	Color change from pink to green	Visual	Each incoming material lot
PET/PP film Bond Strength	N/15mm	>2,7 n/15 mm	ASTM F88	Each film roll
PET/PP film Delaminating	pcs	None Allowed	Steam Ster. 134 °C/ 3,5min.	Each film roll
Aseptic Presentation	pcs	No film or paper tear	Peel off / open slow	Each 2 hour of production
Bioburden Testing	pcs	Run and record	ISO 11737-1	At least every 3 month
Particles/Cleanliness	pcs	None Allowed	Visual	Each 2 hour of production
Microbial Barrier	pcs	Fulfill requirements of ASTM F1608	ASTM F 1608	Internal determined period
Wrinkles in Films or Seals	pcs	None Allowed	Visual	Each 2 hour of production
Jagged Edges	pcs	None Allowed	Visual	Each 2 hour of production
Stewed Printing	pcs	±2 mm	Visual	Each printed roll
Print Image	pcs	Artwork and readable	Visual	Each printed roll

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Labelling and documentation

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(link to www.hawo.TV for the video)

Routine Monitoring

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Routine Monitoring

https://youtu.be/VPvfDI1lXcY

Remember

- ✓ international standard require validation
- ✓ sealers shall monitor the critical process parameters
  - ✓ Temperature
  - ✓ Contact pressure
- ✓ hawo sealers with the ‚-V' at the end fulfil the requirements
- ✓ use a suitable monitoring system (e.g. seal check or inkTest)
- ✓ maintain the sealer annually

hawo

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