

Meeting the challenges of medical device packaging

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Agenda

Evaluation and selection

Validation

Test methods

Sterile Barrier Systems

Standards

- EN 868 Parts 2 – 10

Vertical standards for certain applications (products)

- ISO 11607-1 & 2

- ✓ Part 1: Materials, sterile barrier systems, and packaging systems requirements
- ✓ Part 2: Packaging process validation

The scopes of both of these standards apply to health care facilities and wherever medical devices are packaged and sterilized.

The presentation will focus and provide guidance on interpreting the ISO 11607 to health care facilities. It is recognized that the medical device manufacturer follows additional requirements.

Definitions

- **Sterile Barrier Systems (SBS)** – previously known as primary packaging, the minimum package that prevents the ingress of microorganisms and allows aseptic presentation of the product at the point of use
- **Protective Packaging** – a configuration of materials designed to prevent damage to the SBS and its contents from time of assembly until point of use. Protective packaging is designed to provide additional protection against damage and outside elements, not to provide a microbiological barrier
- **Packaging System** – combination of the sterile barrier system and protective packaging

Preformed sterile barrier system (PSBS)

Common choices

- pouches and reels
- sheets of sterilization wrap
- rigid reusable container



When sealed using a validated process, they become sterile barrier systems.

Evaluation and selection -packaging system –

What are the criteria?

What are the considerations?

Preformed sterile barrier system (PSBS)

- Compliance with ISO 11607
- Appropriate to the method of sterilization
- Suitability for use in specific applications and conditions of use
 - ✓ Compatible with the labeling system
 - ✓ Appropriate for the device(s) under consideration

Evaluation and selection Packaging System

- Provide adequate protection of the medical device(s) during intended specific storage and transportation to the point of use;
- Maintain sterile barrier integrity until its time of use;
- Ensure aseptic presentation at the point of use;
- Provide an adequate barrier to microorganisms;
- Allow for ease of identification of contents;
- Additional protection from the effects of environmental conditions (e.g. direct sunlight) during storage;

Purchasers should evaluate the performance of each packaging system and use this information to determine that conditions for sterilization, shelf life, transport, storage, and handling can be met.

Sealable pouches and reels

The following aspects should be considered:

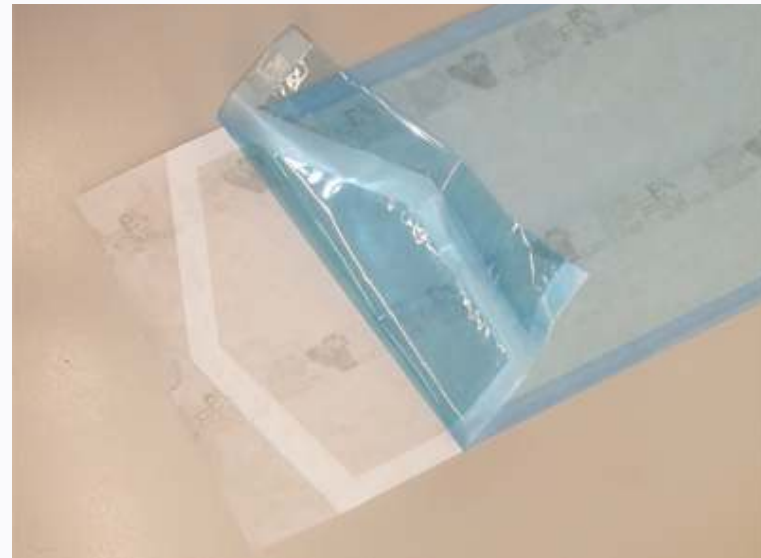


- The size of the pouch and the strength of the packaging materials should be based on the medical device which is going to be packaged.
- The preformed sterile barrier system should be filled up to a maximum of $\frac{3}{4}$ of space.
- When two pouches are used, the inner pouch should be able to move within the outer pouch. This allows penetration of the sterilant and prevents the pouches from sticking together.

For combining two pouches made from film and paper it is important that film meets film and paper meets paper for identification of content and permeation of sterilant.

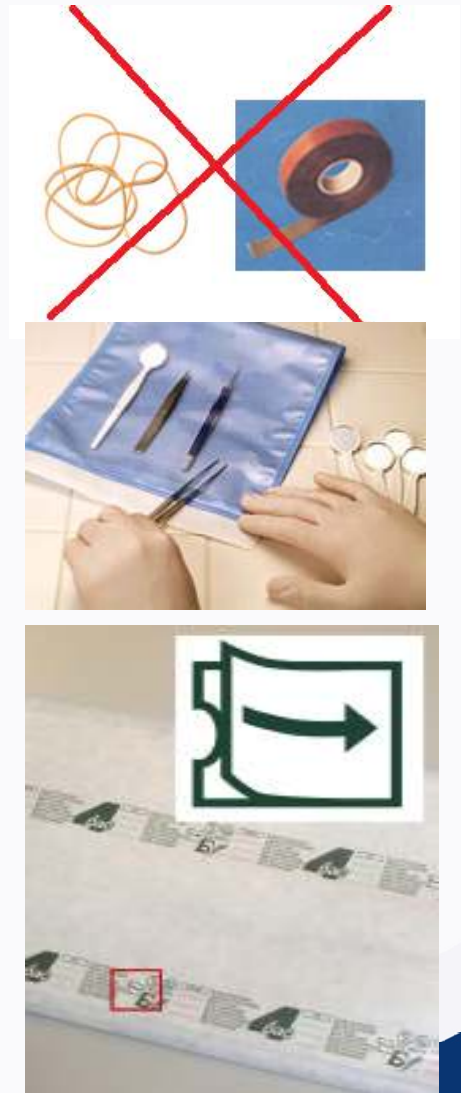
Sealable pouches and reels

- Heat sealing devices should be able to control and monitor critical process parameters (e.g. temperature, pressure, sealing time/speed) in accordance with its validation criteria (e.g. alarms, warning system or machine stop in the event of any critical process parameter deviation).
- The seals should be smooth, i.e. without folds, bubbles, or wrinkles.



Sealable pouches and reels

- Closures that compress the package or device should not be used, (e.g. ropes, string, elastic bands, paperclips, staples or similar items).
- The pouch should be loaded so that the enclosed device will be presented aseptically.
- The pouch should be opened according to the manufacturer instructions. A design should show which direction the packaging has to be open.



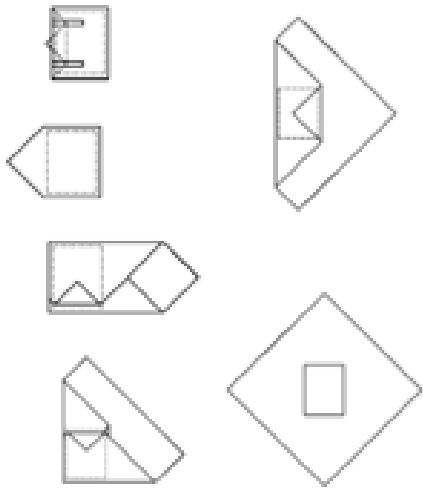
Sterilization wrap

The following aspects should be considered:



- The grade of the sterilization wrap should be chosen according to the size, shape and weight of the package to be wrapped.
- The size of the sterilization wrap should be selected to achieve adequate coverage of the item being packaged. The sterilization wrap should be large enough to cover the medical device, but it should not be so big that it has to be wrapped several times around the medical device, as this may impede sterilant penetration.
- Sequential wrapping using two barrier-type wrappers provides a torturous pathway to impede microbial migration.

Sterilization wrap



- The sterilization wrap should be designed in a manner that the opened wrapper should drape away from the sterile field.
- The wrapped package should be designed in a manner so that all edges are folded in such a way that do not interfere with aseptic presentation into the sterile field.
- The assembly surface area for wrapping should be flat, smooth, of adequate size, well lit and clean.
- Indicator tape is the most common closure for wrapped packages.
- Closures that compress the package or device should not be used.

Performance testing

Testing the performance of a packaging system is a key principle for a good choice.

Performance testing should allow verification on how well the sterile barrier system or packaging system holds up to the rigors of anticipated conditions of handling, distribution and transportation, before and after sterilization: **The sterile barrier system needs to maintain its integrity without any holes, tears or seal/closure rupture that may be caused by the imposed stresses.**

Performance testing

How to do it?

- Evaluate it through all the intended processes of sterilization (multiple exposures, different sterilization processes), handling, distribution and storage, up to the point of use.
- Evaluate it for expected worst case scenarios:
 - ✓ Use the device(s) that apply the most stress
 - ✓ Use the worst case sterile barrier system produced at the process limits of sealing

Validation for forming sealing and assembly processes

-Guidance on conformance to ISO 11607-2 –

Aim

- Avoid failures and reduce risks
- Critical to demonstrate the efficacy and reproducibility of packaging process

A separate validation plan should be used for each different combination of sterilization process and sterile barrier system / packaging system (manufacturer, type, etc.).

Validation for forming sealing and assembly processes

What are the requirements?

- Implementation of validation consisting of:
 - ✓ Installation Qualification (IQ)
 - ✓ Operational Qualification (OQ)
 - ✓ Performance Qualification (PQ)
- Process control and routine monitoring
 - ✓ Procedure for addressing failure and corrective action to be taken;
- Process/packaging changes and revalidation

A validation report should include:

- Responsibilities (i.e. facility, location, name of person responsible for validation and operator);
- Description of sterile barrier system contents;
Rationale for selection of the worst case.
- Sample size (based upon a statistical valid rationale);
- Description of the sterilization process e.g. Steam sterilization at 134 °C and 121 °C, Ethylene Oxide, Gas plasma, LTSF (low temperature steam formaldehyde), including the cycle parameters and loading procedure used;

A validation report should include:

- Description of the sterile barrier systems used;
 - ✓ Type, size, grade and LOT number
 - ✓ Supplier
 - ✓ Does the material comply with ISO 11607-1?
 - ✓ Does the material comply with EN 868-5 (reel and pouch) / EN 868-2 (wrap)?

A validation report should include:

- Description of the operating procedures;

Processes:

- ✓ (heat) sealing of pouches/reels
 - ✓ wrapping: folding and closing of sterilization wraps;
 - ✓ container: filling/loading and closing of reusable containers.
- Description of the protective packaging, if used;
Rationale for selection of the worst case.
 - Description of transport, distribution and storage conditions;

A validation report should include:

- Acceptance criteria;

Determine what attributes(s) will be evaluated, the method of evaluation and the results that will be considered acceptable.

- Qualification steps (IQ, OQ and PQ);
- Validation approval;
- In-process control and routine monitoring;
- Process/packaging changes and revalidation;

Sterile barrier system stability (shelf life)

Loss of package integrity is regarded as event-related rather than time related.

Loss of package integrity depends on the:

- Quality of the sterile barrier system or packaging system
- Storage (environmental) conditions, the conditions during transport and the amount of handling

Sterile barrier system stability (shelf life)

Storage environment considerations

- Prevent any damage
- Controlled environment
- Maintaining temperature and humidity controlled
- Limit exposure to dust and sunlight
- Keep protective packaging in place
- Minimizing handling
- Physical separation of clean and contaminated items
- etc...

Test methods

Test selection

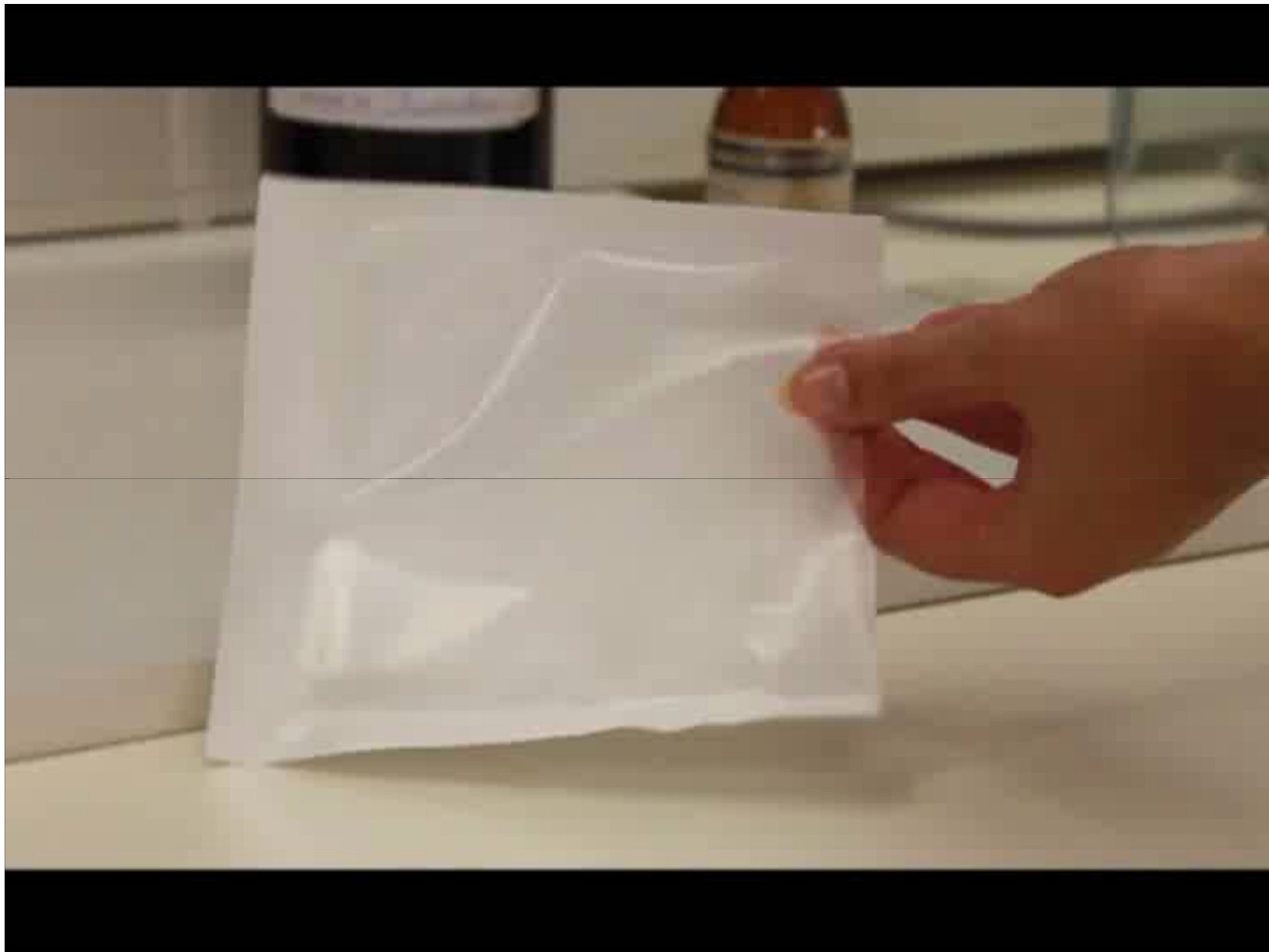
ISO 11607 has 4 pages of suggested test methods

Common Standard Packaging Tests

Integrity test	Strength test
Dye Migration ASTM F1929	Seal Peel ASTM F88
Visual Inspection ASTM F1886	Burst ASTM F1140

Dye penetration test

ASTM 1929



Seal Peel Test

ASTM F88



Burst Test

ASTM F2054



Test Methods - Key Points

- Any test method used for assessing suitability/monitoring of
 - packaging systems
 - packaging materials
 - packaging processneeds to be validated.

This includes in-house methods and standard methods.

- Precision and bias statements that can be found in the standards can help assess any variability found in validation results.

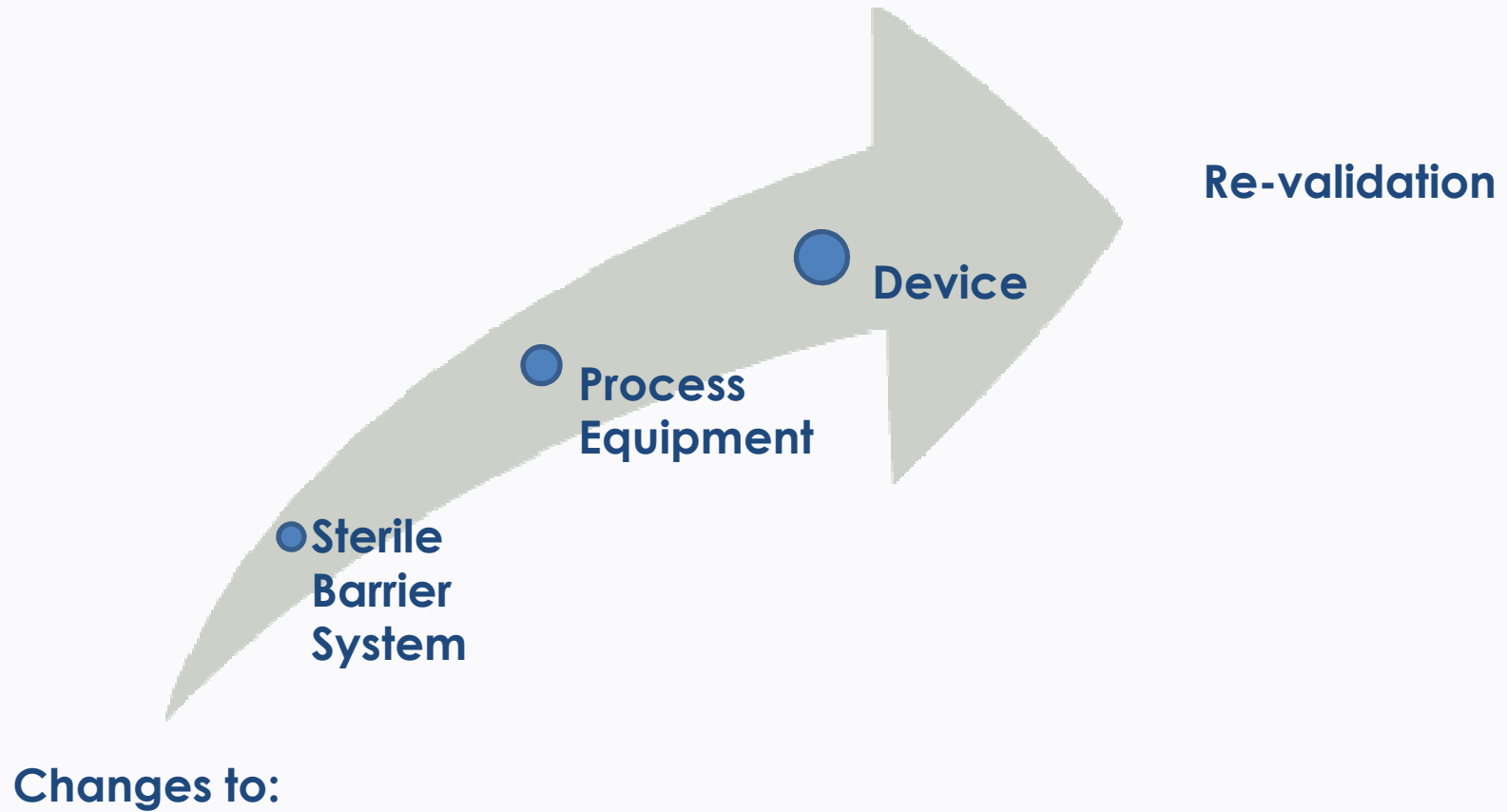
Sealing process – pouch and reel

Attribute	Method for evaluating	Acceptance criteria
Seal integrity	Dye penetration test Visual inspection	Intact and continuous seal Meets specified width No channel No wrinkles, creases or bubbles
Package integrity	Dye penetration test Visual inspection	No punctures, tears or breaks
Seal strength	Seal peel test	1,5 N / 15 mm (Reference value indicated by EN 868-5)
Aseptic presentation	Visual inspection	Able to open without damage or contamination of the contents
Peel ability	Peelable without material rupture, delamination, separation or degradation	Yes/No

Wrapping process

Attribute	Method for evaluating	Acceptance criteria
Closure integrity	Visual inspection (Dye penetration test)	Continuous, no opening or breaches/gaps, no channels
Package integrity	Visual inspection (Dye penetration test)	No punctures, tears, breaks
Aseptic presentation	Visual inspection	Able to open without damage or contamination of the contents
Assembly (folds, etc.) according to documented procedure/assembly instructions	Visual inspection	The opened SBS conforms to the documented procedure/assembly instructions
Packaging configuration processed in the defined cycle	Data-loggers Chemical indicators	Have all sterilization parameters for the defined packaging configuration been met?

Re-validation



“Security is the mother of danger and the grandmother of destruction.”

"A segurança é a mãe do perigo e a avó da destruição."

Thomas Fuller

Thank you!