validation of heat sealing processes

ISO 11607 part 2
“every chain is only as strong as its weakest link”
our chain | Instrumental Preparation

washing disinf. | packaging | sterilization | aseptic presentation
only the packaging system is responsible for maintaining sterility to the point of use

the packaging process is one of the most important links in the instrument preparation chain
... every SBS packaging process shall be validated!

sterilization sheets folding and wrapping

pouch, reel, or bag forming and sealing

filling and closing of reusable containers
What does validation mean?

A documented procedure for obtaining, recording, and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications.
what does it mean in plain words?

- the process must be documented and controlled
- the process must always function in the same way
- the process must be repeatable and reproducible
2 general requirements for the heat sealing process

only use professional packaging machines which guarantees reproducible processes
2 general requirements for the sealing process

"only use professional packaging material in accordance with the international standard"
...now we are prepared for

the process validation
the validation consists of 3 steps ...

Installation Qualification | IQ

Operational Qualification | OQ

Performance Qualification | PQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification
Installation Qualification | the meaning

the machine must be suitable

the user must be trained

use a check list ...
Installation Qualification | the check list

- are the users trained (who, how)?
- is the training certified?
- are operating instructions available?
- is an authorized service team known?
- is the sealer correctly connected?
- does the sealer have no defects?
- does the process run automatically?
- and independently of the user?
- are the critical parameters documented?
- are the ambient conditions constant?
- are written schedules for service available?
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures
Operational Qualification | the meaning

process parameters shall be challenged (e.g. temperature)

sterile barrier systems shall be produced at upper and lower parameter limits

→ to simulate “real life”
the following quality properties shall be considered

- intact seal for a specific seal width
- no channels or open places
- no punctures or tears
- no material delamination or separation

- furthermore the specified requirements (part 1) for seal strength shall be met
2. bags have to be sealed at the upper and lower temperature level

3. quality properties have to be checked | seal indicator or ink test (EN 868-1)

4. seal strength has to be measured | Peel Test (EN 868-5 or ASTM F88)
in accordance with the standard EN 868-5 Appendix D

→ it has to be evaluated whether the minimum seal strength is greater than 1.5 N

→ strong enough to withstand the stress of sterilization
process of obtaining and documenting evidence that the equipment consistently performs in accordance with predetermined criteria and thereby yields product meeting its specifications
shall demonstrate that the process will consistently produce acceptable SBSs under specified operating conditions

→ sealed bags must be strong enough packaged to “survive” the sterilization process (e.g. 134°C | 121°C)
Performance Qualification | the procedure

1. sampling
   seal bags under specific operating conditions and take samples

2. production running
   sterilize 3 production runs to demonstrate reproducibility between different runs

3. testing
   test bags to proof that they are properly closed after the stress of sterilization (e.g. with Peel Test EN 868-5)

4. formal approval
finally | after passing the qualification

the process has to be monitored and under control

the critical process parameters shall be routinely monitored and documented

- can be done manually
- automatically by the sealer
- by connecting the sealer to tracking systems
process is now validated!
... please remember

- this International Standard will be applicable to industry, health care facilities and wherever medical devices are placed in sterile barrier systems and sterilized

- every CSSD must be equal to these requirements and will be considered as a manufacturer
It is in the end a question of PATIENT SAFETY
thank you for listening!

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