Guideline for the validation of packaging processes according to DIN EN ISO 11607-2
A guideline for the validation of packaging processes?

Why ???

What have been the motives for developing this guideline?
The work group's motives for developing the guideline

It has been worked on the guideline for this process already in detail within the 1st revision of the guideline in 2008
The work group's motives for developing the guideline

✓ A guideline for pouch, reel or bag sealing exists already

• Well – what about the other packaging processes?
• Don't they play a role within the whole process?
• How do those packaging processes fit into the validation of sterilization processes?
The work group's motives for developing the guideline

What is the focus for bought-in packages:

• Quality?
• Price?
• Who decides which packages, which quality will be bought?
• Do these products accord to normative requirements?
• Do validated processes play a role?
The work group's motives for developing the guideline

- Dissatisfaction of people working with topics as cleaning, disinfection and sterilization of medical devices as well as users, e.g.:
  - Gluing of packages
  - Materials which are difficult to handle
  - Poor quality of adhesive tape
  - …
The work group's perspective:

The guideline for the pouch, reel and bag sealing is the beginning in the validation of packaging processes.

We asked ourselves, does it make any sense to continue with our work?

What was our purpose continuing with this work?
The workgroup's purpose

- Realization of legal guidelines
- Validation of the whole process
- Process reliability for the safety of patients and staff
Validated processes?

Yes - automated cleaning and disinfection processes

Yes - heat sealing processes

Yes - sterilization processes
... and the manual processes?

- Manual cleaning and disinfection processes
- Visual inspections
- Maintenance process
- Operational qualification
- Packaging of medical devices
  - Sample standard operating procedure heat sealing
  - Sterilization sheet's folding and wrapping
  - Filling and closing of reusable sterilization containers
- Approval
- Storage and transport
... and the manual processes?

✓ Manual cleaning and disinfection processes

  Visual inspection
  Maintenance process
  Operational qualification

✓ Packaging of medical devices in pouches, reels and bags
✓ Soft packaging (Sterilization sheet's folding and wrapping)
✓ Container packaging (reusable container)

Approval

⇒ Storage and transport
Without a Quality Management System a validation is not possible. All steps have to be defined and documented.
## Normative bases for writing this guideline:

<table>
<thead>
<tr>
<th>Standard</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIN 58953, Part 7 (2010)</td>
<td>Application technique of sterilization sheets, heat sealable transparent bags and tubing</td>
</tr>
<tr>
<td>DIN 58953, Part 8 (2010)</td>
<td>Logistics of sterilized medical devices</td>
</tr>
<tr>
<td>DIN 58953, Part 9 (2010)</td>
<td>Application technique of containers</td>
</tr>
</tbody>
</table>
When using sterilized medical devices the packaging is part of the sterilization process and therefore the packaging is to validate as well.
The packaging process

Pouch, reel or bag sealing

Sterilization sheet's folding and wrapping

Filling and closing of reusable containers
Validation using the example of the following packaging process:

Folding and wrapping of sterilization sheets
Initial validation

Initial operating
Agenda

Requirements

Drafting of a validation plan

Conduct of validation

Drafting of a validation report

Formal approval of the validation process

Process control and monitoring

Process changes and revalidation

Table of the process validation
The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation
Requirements

Request supporting documents by the manufacturer:

• CE confirmation of conformity = European minimum requirement for quality and product safety
• ISO 11607 / EN 868
• Product specification and/or technical data sheet
• ISO 9001 certificate
The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation
Drafting of a validation plan

Content:
• Competences
• Description of the packaging process
• Description of the materials/equipment
• Description of another indicator used
• Description of sterilization process
• Qualification steps (IQ, OQ, PQ)
• Formal approval of validation/revalidation by the operator
Validation plan checklist „sterilization sheets´ folding and wrapping“
### Competences

<table>
<thead>
<tr>
<th>Name of Institute (or department)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Location</td>
<td>--</td>
</tr>
<tr>
<td>Validation (name of persons, or company, conducting validation)</td>
<td></td>
</tr>
<tr>
<td>Responsible (name of inst. or organisation)</td>
<td></td>
</tr>
</tbody>
</table>

### Description of reusable containers

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Designation</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buyer/wh</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Material</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of packaging material (text)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of packaging material (text)</td>
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<td></td>
</tr>
<tr>
<td>Description of packaging material (text)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

All check marks must be affixed to the overpackaging. The C1 mark can be prefixed to the overpackaging by the manufacturer or professional of the manufacturer.

All labels in accordance with EN 1784-1 for disposable particulate filters, EN 13485 for reusable particulate filters, EN 13485 for reusable particulate filters, and EN 13485-1 for reusable particulate filters are essential. The filters are marked with the relevant marks.
The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation
Sterilization sheets folding and wrapping

Process validation in 3 steps

Validation

Installation qualification IQ
Operational qualification OQ
Performance qualification PQ
Definition:
„Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with the specification.“
• Technical equipment must have been properly installed

• Users/staff must have been trained and standard operating procedures are known (documentation of training of staff)
Standard operating procedures?

Diagonal packaging

Installation qualification IQ
Standard operating procedures?

Parallel packaging:
# Installation qualification (IQ) checklist

**Annex B.2: Installation qualification (IQ) checklist «sterilization sheets’ folding and wrapping»**

<table>
<thead>
<tr>
<th>Are standard operating procedures available (SOPs)?</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ Yes □ No □ Where?</td>
</tr>
<tr>
<td>(e.g., as in Annex B.6)</td>
</tr>
</tbody>
</table>

## a) Training

<table>
<thead>
<tr>
<th>Name of trained staff member</th>
<th>Training</th>
<th>Signature</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>By</td>
<td>Qualification</td>
</tr>
</tbody>
</table>

Only if all users are inducted/trained will installation qualification be deemed to have been passed.
**Definition:**

„Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures.“
• Packaging systems –
  – sterile barrier systems and
  – packaging materials

→ double checking of the quality properties is necessary
Number of samples: 10
(photographic documentation)

- Continuous closeness/integrity
- No punctures or tears
- No other visible damage or material irregularities
**Annexe B.3: Operational qualification (OQ) checklist «sterilization sheets' folding and wrapping»**

If the packaging system is composed of a sterile barrier system and protective packaging, the quality properties of both the sterile barrier system and protective packaging have to be verified for OQ.

<table>
<thead>
<tr>
<th>Requirement for sample size (S)</th>
<th>S ≥ 10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample size (S)</td>
<td>S =</td>
</tr>
<tr>
<td>Compliance with requirement</td>
<td>□ Yes  □ No</td>
</tr>
<tr>
<td>Quality properties</td>
<td>Compliance</td>
</tr>
<tr>
<td>Intact closeness/integrity</td>
<td>□ Yes □ No</td>
</tr>
<tr>
<td>Evidence based on</td>
<td></td>
</tr>
<tr>
<td>Test method:</td>
<td></td>
</tr>
<tr>
<td>Name/signature</td>
<td></td>
</tr>
<tr>
<td>No punctures (perforation) or tears</td>
<td></td>
</tr>
<tr>
<td>Protective packaging</td>
<td>Sterile barrier system</td>
</tr>
<tr>
<td>□ Yes □ No □ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Evidence based on</td>
<td></td>
</tr>
<tr>
<td>Test method:</td>
<td></td>
</tr>
<tr>
<td>Name/signature</td>
<td></td>
</tr>
<tr>
<td>No other visible damage or material irregularities</td>
<td></td>
</tr>
<tr>
<td>Protective packaging</td>
<td>Sterile barrier system</td>
</tr>
<tr>
<td>□ Yes □ No □ Yes □ No</td>
<td></td>
</tr>
<tr>
<td>Evidence based on</td>
<td></td>
</tr>
<tr>
<td>Test method:</td>
<td></td>
</tr>
<tr>
<td>Name/signature</td>
<td></td>
</tr>
</tbody>
</table>

To document the quality properties, it is recommended that at least one photo be taken in addition of each sample.
Definition:
“Process of obtaining and documenting evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields products meeting its specification.”
• Sterilized packaging systems must be taken from the running processes
• From 3 different cycles (batches) one sample must be taken in each case
• Assurance of the quality must be verified for each packaging
• Compliance with the defined packaging techniques
• Photographic documentation
Photographic documentation:

Opening step by step «sterilization sheets»
### Performance qualification (PQ)

#### Annex B.4: Performance qualification (PQ) checklist for sterilization of packing and wrapping

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Batch 1A</th>
<th>Batch 1B</th>
<th>Batch 1C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Decontamination</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inspiration and exposure</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Registration professional and current license documented</td>
<td>Yes</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

#### Quote Record A: quality properties

<table>
<thead>
<tr>
<th>Quality property</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization efficacy</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterilization based on</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterilization based on visual inspection</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterilization based on microbiological test</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

#### Quote Record B: quality properties

<table>
<thead>
<tr>
<th>Quality property</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization efficacy</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterilization based on</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterilization based on visual inspection</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterilization based on microbiological test</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>

#### Quote Record C: quality properties

<table>
<thead>
<tr>
<th>Quality property</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilization efficacy</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Sterilization based on</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterilization based on visual inspection</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Sterilization based on microbiological test</td>
<td>Yes</td>
<td></td>
</tr>
</tbody>
</table>
The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation
Drafting of a validation report

Content of the validation report:

- Validation plan
- Evidence of implementation of the validation plan (IQ, OQ, PQ checklists)
- Evaluation of the results
- Photographic documentation for manual packaging processes
- Details and explanation of any deviations from validation plan
- Formal approval of validation
- Process control and monitoring
- Process changes and revalidation
The practical cycle with the help of the guideline

→ Requirements
→ Drafting of a validation plan
→ Conduct of validation
→ Drafting of a validation report
→ Formal approval of the validation process
→ Process control and monitoring
→ Process changes and revalidation
→ Table of the process validation
Formal approval of the validation process

Validation must be formally approved and duly documented by the competent person appointed by the operator

- Therefore a field is provided in the validation plan

! Clear documentation of not accepted results including assessment of any remaining risks
The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
- Formal approval of the validation process
- Process control and monitoring
- Process changes and revalidation
- Table of the process validation
Process control and monitoring

One result of the validation – Necessary routine tests for on time recognition of changes in the packaging process

Preservation of the requirements of the sterile barrier systems
Process control and monitoring

e.g. in standard operating procedures

**Routine tests** are for example:
- Visual inspections
- Stepwise opening of packaging

**Definition of**

- Intervals of conducting the routine tests (e.g. daily, weekly, monthly, yearly, …)
- Acceptance values
- Way of the documentation
The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
- Conduct of validation
- Drafting of a validation report
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- Process changes and revalidation
- Table of the process validation
Process changes and revalidation

Unscheduled Revalidation:
• e.g. in the event of changes to
  – Materials
  – Processes
  – Sterilization

Scheduled Revalidation:
• If there are no changes
• at regular intervals, general after one year
The practical cycle with the help of the guideline

- Requirements
- Drafting of a validation plan
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- Table of the process validation
Validation of packaging processes:

sterilization sheets´ folding and wrapping

How is the amount of necessary checks measured?
### Table of the process validation

<table>
<thead>
<tr>
<th>Packaging</th>
<th>STEAM 134 °C/5 min</th>
<th>STEAM 134 °C/18 min</th>
<th>STEAM 121 °C/20 min</th>
<th>FORM (formaldehyde)</th>
<th>EO (ethylene oxide)</th>
<th>VH202 (plasma)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Material A (crepe paper)</td>
<td>×</td>
<td>×*</td>
<td>×</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material B (nonwovens)</td>
<td>×</td>
<td>×*</td>
<td>×</td>
<td>x*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material C (SMS nonwovens)</td>
<td>×</td>
<td>×*</td>
<td>×</td>
<td>×*</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Material D (textile materials)</td>
<td>×*</td>
<td></td>
<td></td>
<td></td>
<td>×*</td>
<td></td>
</tr>
</tbody>
</table>

The 13 combinations outlined in the table can be reduced by taking account of only the maximum material stress (worst-case scenario, while providing documentary proof to justify this; in this example for material A, B and C: 134 °C/18 min). These combinations are marked with an ×* in the table. This shows that in this example validation needs to be carried out in total seven times. A further reduction can be achieved by a deliberate sterile barrier system (e. g. by using only two different materials). Accordingly, for this example the number of validations would be reduced from seven to five or even four.

Note: When using packaging sheets for FORM or EO sterilization one must ensure that the maximum residual content of sterilant permitted is not exceeded.
• This was an example of the validation of a manual packaging process.

• The process for the validation of containers and pouch, reel and bag sealing have the same structure
The purpose of our work:

For operators and all persons related to medical device reprocessing:

– Showing the possibility to validate the total packaging process
– Providing a practical orientation guide for a validation according to DIN EN ISO 11607-2
Purpose of this guideline

This guideline supports …

- … in **structuring** processes
- … in **optimizing** internal processes
- … the **control and monitoring** of processes
- … the Management of sterilization departments in their **preparations**
The purpose of our work:

- Approaching a uniform comprehension for operators, validators, supervisory authorities and certification bodies

- Uniform and correct conduction of the validation of packaging processes

Not at least to avoid confusion!
Thank you for your attention!

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