Guideline for the validation of the sealing process according to DIN EN ISO 11607-2, revision 01, July 2008

Foreword to the guideline

The highest goal of every packaging system for medical devices, which are terminally sterilized, is the assurance of sterility until the products are used on the patient. The validation of packaging processes is crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

The seam sealing process in the context of the preparation of medical products should be seen as a part of a chain of procedures.

The international standard EN ISO 11607, part 2, describes the validation of the packaging process. It serves as the basis for the drafting of this guideline which should be understood as an orientation aid for the successful implementation of validation in reprocessing practice.

Through experience with the implementation of validation guidelines for the sterilization process and cleaning/disinfection processes, it has become clear that a reliable manual with a practical orientation for the implementation of the standardizing requirements is necessary in order to achieve as uniform as possible understanding by operators and validators. The focus on the uniform and correct implementation of the validation of the sealing process is of great importance for all involved in the process as well as for the monitoring and certifying authorities, and finally to minimize confusion.

The authors would like to point out that this guideline is intended as a practical aid and should serve merely as a guide. There is no guarantee of completeness.

Authors of the guideline:
A. Carter, A. Jones, K. Wiese (Deutsche Gesellschaft für Sterilgutversorgung, DGSV e.V.)
Dr. A. Johmann, Dr. H.Ch. Lüdtke-Handjery (Zentralstelle der Länder für Gesundheitsschutz, ZLG)
Dr. T. Kießling, Dr. G. Oberländer, Dr. J. Breder (TÜV Rheinland GmbH)

Table of contents

1 Scope 2
2 International Standard basis 2
3 Conditions 2
4 Validation of the sealing process 2
4.1 The Drafting of a validation plan 2
4.2 Implementation of validation 3
4.2.1 Installation Qualification (IQ) 3
4.2.2 Operational Qualification (OQ) 4
4.2.2.1 Peeling test 4
4.2.2.2 Quality properties 4
4.2.3 Performance Qualification (PQ) 4
4.3 Compiling of the validation report) 5
4.4 Validation approval 6
4.5 Process control and routine monitoring 6
4.6 Specifications for revalidation 6
5 Appendices A-E 7
5.1 Appendix A: Validation plan checklist, page 1 of 2 7
Appendix A: Validation plan checklist, page 2 of 2 8
5.2 Appendix B: Checklist Installation Qualification (IQ), Page 1 of 3 9
Appendix B: Checklist Installation Qualification (IQ), Page 2 of 3 10
Appendix B: Checklist Installation Qualification (IQ), Page 3 of 3 11
5.3 Appendix C: Checklist Operational Qualification (OQ), Page 1 of 1 12
5.4 Appendix D: Checklist Performance Qualification (PQ), page 1 of 1 13
5.5 Appendix E: Example for determining the scale of the process validation for each sealing device 14

1 Scope

According to the standard EN ISO 11607-2 the validation of the packaging processes is applicable to industry, to health care facilities and wherever medical devices are packaged and sterilized (examples include hospitals, doctors and dental surgeries).

2 International Standard basis

The EN ISO 11607, part 2 explicitly postulates validation of all preformed sterile barrier systems and sterile barrier system manufacturing processes (sealing, sterilization sheets folding and wrapping, filling and closing of reusable containers, etc.). This guideline treats the sub-area of 'sealing'.

According to the current state of knowledge, self-sealing packaging materials are not able to achieve permanent impermeability. Similarly, the reproducibility of this packaging process cannot be insured. This guideline is therefore not applicable in this case.

3 Conditions

The packaging materials used must be appropriate for and determined by the intended sealing and sterilization process. The manufacturer can verify the suitability. Confirmation of conformity with the EN ISO 11607-1 and the appropriate parts of the norm series EN 868, part 2-10 (e.g. EN 868-5 for sealable reels and pouches) include the following:

- Bacterial impermeability
- Sealing procedure and temperature range
- Sterilization procedure

The process parameters of the sealing devices must be verifiably calibrated in compliance with EN ISO 11607-2, 5.2.5. This can be done by the manufacturer or an accordingly accredited test laboratory.

The testing of sealed and sterilized transparent pouches can, for example, be carried out in an accredited test laboratory or by a competent validator.

4 Validation of the sealing process

Fundamentally, a documented method of validation must exist. This consists of:

4.1. Drafting of a validation plan

4.2. Implementation of the validation plan

4.2.1. Installation Qualification (IQ)

4.2.2. Operational Qualification (OQ)

4.2.3. Performance Qualification (PQ)

4.3. Installation of validation report

4.4. Validation approval

4.5. Specification of monitoring routine

4.6. Specification of revalidation of required parameters

4.1 The Drafting of a validation plan

At a minimum, the validation plan should include the following information:

- Responsibilities
- Description of the sealing procedures
- Description of the materials used
- Description of the sterilization process

- Qualification steps (IQ, OQ and PQ)

The validation plan checklist in Appendix A can be used. A separate checklist should be used for each different combination of sterilization procedure and packaging material (manufacturer, type, etc.— but not for pouch size).

With the following table, the number of executed process validations per sealing device can be determined and defined (see example in Appendix E).

Sealing device	Steam			NTDF	ETO	H_2O_2
	134°C/5 min	134°C/18 min	121°C/20 min			
Material A						
Material B						
Material C						
Material D						

The possible combinations from the table can be reduced as only the maximum stress of the materials needs be accounted for (the so-called 'worst-case' scenario with documented rationale). A further reduction can be achieved by conscious selection of packaging materials (e.g. larger transparent pouches instead of pouches with side folds, transparent pouches instead of paper bags).

4.2 Implementation of validation

4.2.1 Installation Qualification (IQ)

Definition: "Process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification."

This means that the sealing device must be appropriate and correctly installed. In addition the user must be trained. The following questions should already be clarified in the forefront:

- Are the critical process parameters defined (the critical process parameters are at minimum temperature and contact pressure)?
- Is the sealing temperature for materials to be used defined based on the manufacturer's specifications?
- Does the sealing device have mechanisms at its disposal, which control, monitor and document the critical process parameters?
- In the case that previously determined thresholds are exceeded, is a warning system or alarm device activated or will the machine be halted?
    - According to the guidelines in DIN 58953-7 (German Standard) this must occur when the variation in temperature is greater than ±5 °C.
- Are the security criteria (seal seam width and the required distance to the medical product) according to DIN 58953-7 satisfied?
- Do written plans for maintenance and cleaning exist?
- Are all users demonstrably trained and briefed?

For implementation of the Installation Qualification (IQ) the use of the appropriate checklist is recommended. The Installation Qualification (IQ) checklist in Appendix B can be used for documentation purposes.

4.2.2 Operational Qualification (OQ)

Definition: "Process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures."

First, the threshold values for the variable critical process parameters must be defined. Normally this involves only the temperature. Sealing time and speed and contact pressure are, as a rule, rigidly and permanently defined. The threshold values are typically the temperature guidelines (upper and lower limits) as defined by the manufacturer of the sealable pouches and reels.

Finally, the process parameters shall be challenged. Therefore, test sealings must be produced with the temperature values at the upper and lower limits. The sterile barrier system must be peelable and satisfy all quality properties of the seal under all the foreseeable manufacturing conditions.

4.2.2.1 Peeling test

By carrying out the peeling test it is subjectively checked, whether the sealing seam can be manually opened without difficulty. At the same time, the sealing seam must not be sheered, or rove, because this can lead to contamination. The result of the test is to be documented.

4.2.2.2 Quality properties

According to EN ISO 11607-2, section 5.3.2 b, the quality properties for sealing are as follows::

- Intact seal for a specified seal width.
- No channels or open seals.
- No punctures or tears.
- No material delamination or separation.

These quality properties must be checked and documented through the appropriate operation. For example, the ink test and/or the "Seal Check" can be used.

For this purpose, two seals must be made, one at the upper and one for the lower limit temperature. For both seals, the quality properties must be satisfied.

Afterwards the sealing temperature to be used in daily operation must be defined. It is recommended to use the average value between upper and lower level temperature during the test.

The Operational Qualification (OQ) checklist in Appendix C can be used for documentation purposes.

4.2.3 Performance Qualification (PQ)

Definition: "Process of obtaining and documentation evidence that the equipment, as installed and operated in accordance with operational procedures, consistently performs in accordance with predetermined criteria and thereby yields product meeting its specification."

With the Performance Qualification, evidence must be produced that the process is controlled and - also after sterilization - yields an optimum sterile barrier system.

PQ ist carried out by means of the seal strength test according to EN 868-5, Appendix D. The packaging must be sterilized prior to the test. The protocol (batch documentation) of the sterilization process is part of the validation.

As stated in the validation plan's defined combinations (see also Appendix E) 3 pouches or reel packages of the same material are to be sealed at the defined temperature and subsequently sterilized with the defined sterilization program (reels must be sealed at both ends). Every pouch must be assigned to a different sterilization batch (as far as available) in order to demonstrate reproducibility within influencing variables.

The test (according to EN 868-5 Appendix D) is carried out as follows:

- Cuts are taken of the dry sample[1] of 15 mm width in a 90° angle for the seal seam. For every sealing 5 samples are selected.
- Simulation of the peeling process at a speed of 200 mm/min.
- Recording of the seal seam resistance process[2].
- Evaluation and documentation of the results.

The results of the seal seam resistance test are confirmed by a report, which contains at minimum the following information:

- Brand and type of sealing device.
- Sealing device serial number.
- Indication of the critical parameters.
- Device tested /most recent calibration.
- Graphic display of the resistance process.
- Maximum resistance of seal seam of N/15 mm width.

An accredited test laboratory or an suitable validation expert can, for example, carry out the testing of the sealed and sterilized transparent bag.

In total 3 bags are to be tested, each labeled clearly, in order that the results can be correctly related to the validation plan (e.g. device manufacturer device designation, machine number and sealing parameters).

5 samples are to be taken from every pack. That results in 15 samples per test, whose maximal seal strength should be entered in the table in Appendix D[3]. The maximal seal strength is the relevant value for the qualification and according to EN 868-5 must be greater than 1.5 N/15 mm width. If the tensile strength in one of the 15 samples is less than 1.5 N the PQ has failed.

The checklist for the Performance Qualification in Appendix D can be used for documentation purposes.

4.3 Compiling of the validation report

The procedural method of validation and the results must be documented in a summary report. The checklists and protocols employed (and photos, where appropriate) are evidence and should be included as appendices. The report can also include the evaluation of the results.

The report must as a minimum consist in the following:

- Validation plan
- Evidence of the implementation of the validation plan (e.g. a filled out checklist pursuant to Appendices B - E)
- Evaluation of the results
- Description and reasoning for any deviance from the validation plan
- Approval of validation
- Specification of routine monitoring
- Specification of re-validation

---

[1] In case of use of wet samples a contact pressure of 1.2 N is sufficient. This method, however, is not common in medical practice.

[2] For further evaluation and documentation it makes sense, that the maximum (recommended by EN 868-5 Appendix D.3) and average tensile strength is documented as a value.

[3] When the homogeneity of the seal seam is demonstrably secure, the scope of the test can be reduced if necessary. The reason for this is to be documented.

4.4 Validation approval

The documented and evaluated validation in the report must be traceably approved by the responsible operator. This can be done, for example, in a previously determined field in the validation plan. In the case that not all results of the validation are accepted, this must be traceably documented including the evaluation of possible remaining risks.

In so far as limitations are determined during the validation procedures, these are recorded in the documentation (e.g. consideration of materials or process parameter whose adequacy could not be verified).

4.5 Process control and routine monitoring

As the result of validation, required and recognized routine tests must be defined (standard operating procedures). It should be ensured that changes in the sealing procedure are made known in sufficient time to avoid the situation that a sealing seam no longer satisfies the requirements. These tests could be for example:

- Peeling test
- Ink test
- „Seal-Check“
- Tensile strength of seal seam
- Visual control

Time interval (e.g. daily, weekly, or monthly) and acceptable values must be defined for the necessary routine tests, including the procedure to be followed if the test result is not satisfactory Results have to be documented.

The critical process parameters shall be routinely monitored and documented. Various methods are known for use in the daily routine:

- Handwritten log,
- Routinely recorded on paper or packaging by means of an integrated printer or
- Connection of the sealing device to an electronic documentation system.

4.6 Specifications for revalidation

Revalidation is carried out

- According to plan, i.e., as a rule, after one year, when no change in materials, sealing procedures and sterilization process has occurred.
- Extraordinary revalidation, i.e., in case of change in materials, the sealing process, including changes on the sealing device or during sterilization processes.

Not all changes in material, sealing procedures or sterilization require revalidation. Fundamentally, a documented assessment is required. In so far as a revalidation is deemed unnecessary, it must be comprehensibly documented.

Scheduled revalidation serves to verify that the sealing process, as was determined through validation (IQ, OQ and PQ), lies within acceptable limits. In this regard, in general, only a Performance Qualification (PQ) has to be carried out. When compared with the previous validation, no changes in materials, sealing procedure and sterilization were carried out; this must be confirmed in the revalidation report.

In the case of an extraordinary revalidation, it must first be determined what influence the changes may on the result of the sealing process. The result is to be documented. Based on that, an individual validation plan must be set up. For example, in the case of changes in materials, the Operational Qualification (OQ) and Performance Qualification (PQ) must be repeated in part or completely . In case of changes to the sealing device or sealing process the Installation Qualification (IQ has to be repeated

During revalidation it is to be secured that the documents used meet the currant requirements. The checklists are to be updated wherever and whenever necessary.

5 Appendices A-E

The checklists available in the appendix can be used for the implementation and documentation of the validation.

5.1 Appendix A: Validation plan checklist, page 1 of 2

☐ **Validation** ☐ **Revalidation**

a) Responsibilities

Name of facility	
Location	
Validator *(Name of persons and, if necessary, the management carrying out the validation)*	
Person responsible for the entire validation (operator)	

b) Description of the sealing device

Sealing device manufacturer			
Designation/type			
Serial number			
Switch-off tolerance of the temperature according to DIN 58953-7 (± 5°C)	☐ yes	☐ no	
Supplier			
Last calibration			
Contact person			

c) Description of materials

Manufacturer			
Designation			
Is the QM certificate of the manufacturer available?	☐ yes	☐ no	
Supplier			
Contact Person			
CE- conformity?	☐ yes	☐ no	☐ verification
Specification of the porous material (*e.g. 80 Gram/Tyvek 1053B)*			
EN 868-5 conformity?*	☐ yes	☐ no	☐ verification
EN ISO 11607, part 1, conformity?*	☐ yes	☐ no	☐ verification
Sealing temperature range (in °C)*	from _____to _____ Data from:_____ ☐ Verification available		
Compatible to sterilization procedure	☐ yes	☐ no	

The information marked with * must be according to EN 858-5 and EN ISO 11607-1 respectively be provided by the packaging materials' manufacturer.

Appendix A: Validation plan checklist, page 2 of 2

d) Description of sterilization processes

Manufacturer and description			
Serial number of sterilizer			
Sterilization process	☐ Steam (highest temp./longest time) ☐ Ethylene oxide (ETO) ☐ Plasma ☐ Formaldehyde (FO) ☐ other_____		
Process validated?	☐ yes	☐ no	
Validator :			
Last validation:			
Next validation:			

e) Qualification steps

Installation Qualification (IQ)	☐ executed	
	☐ already executed in the validation on _____	
	☐ passed	☐ failed
	Date/Signature:	
Operational Qualification (OQ)	☐ executed	
	☐ already executed in the validation on _____	
	☐ passed	☐ failed
	Date/Signature:	
Performance Qualification (PQ)	☐ executed	
	☐ passed	☐ failed
	Date/Signature:_____	

f) Approval of the validation by the operator

☐ All parts of the validation passed

☐ The following parts of the validation failed (please name):

☐ Follow-up actions were determined and documented

_____
Signature

_____ _____
Place, Date Name in block print

5.2 Appendix B: Checklist Installation Qualification (IQ), Page 1 of 3

a) General data

Device (designation/number)				
Manufacturer				
Manufacturer's address				
Quality management system	☐ Verification available			
Type designation				
Serial number				
Year of manufacture				
Location				
Person responsible for validation				
Additional testers for IQ				
Date of test				
Type of device	☐ Bar/impulse		☐ Series device	
	☐ Bar/continuously heated		☐ Special device from manufacturer	
	☐ Rotary sealer		☐ Modified device modified by:	
CE conformity?		☐ yes	☐ no	☐ verification
DIN 58953, section 7 compliance?		☐ yes	☐ no	☐ verification
Service team				
Address				
Telephone number				
Contact person				
Authorization	☐ Yes, by:_____ ☐ No			

b) Installation conditions

Parameter	**Postulated**	**Available (measured)**
Voltage in Volt		☐ yes
Frequency in Hz		☐ yes
Safeguarding in Ampere		☐ yes
Air capacity (with vacuum)		☐ yes
Compliance	☐ **Yes** ☐ **No**	**Date/Signature:**_____

c) Documentation

Document	**Available**		**Location (repository)**
Instruction manual	☐ yes	☐ no	
CE-Declaration of conformity	☐ yes	☐ no	
Replacement parts Order-List	☐ yes	☐ no	
Compliance	☐ yes	☐ no	**Date/Signature:** _____

Appendix B: Checklist Installation Qualification (IQ), Page 2 of 3

d) Security characteristics

Parameter	Postulated		Available	
Seal seam width	6 mm			
Distance to medical product	30 mm			
Process course	automatic		☐ automatic	☐ manual
Compliance	☐ yes	☐ no	**Date/Signature:** _____	

The service instructions in general suffice for verification of these aspects. Furthermore, the following aspects must be checked by an authorized person:

Description	Compliance		Remarks
Is the sealing device connected according to requirement?	☐ yes	☐ no	
Demonstrated that the sealing device has no optical security defects (defect in the case, power supply line, plug, etc.)?	☐ yes	☐ no	
Demonstrated that the sealing device has no operational defects (unknown running noises, rattling, squeaking, etc.)?	☐ yes	☐ no	
Compliance	☐ yes	☐ no	**Date/Signature:** _____

e) Critical Parameters

The following additional aspects must be determined by the user or checked (partial verification required):

Which parameters were designated as critical during process development? (Ask the manufacturer). at least Temperature and contact pressure	☐ Temperature	☐ Contact pressure
	☐ Sealing time	☐ Sealing speed

Question	Compliance		How
Are these critical process parameters controlled and monitored?	☐ yes	☐ no	
Are systems available, which in case of deviation from previously determined limit values of operational parameters raise an alarm or warning or a stop of the machine will be initiated?	☐ yes	☐ no	
Are these critical process parameters routinely documented?	☐ yes	☐ no	
Compliance	☐ yes	☐ no	**Date/Signature:** _____

Appendix B: Checklist Installation Qualification (IQ), Page 3 of 3

The following additional aspects must be confirmed with verification:

Question	Compliance		Proven by
Is the sealing device maintained/ and do written maintenance plans exist?	☐ yes	☐ no	
Are the decisive instruments for the process calibrated and do written calibration plans exist?	☐ yes	☐ no	
Compliance	☐ yes	☐ no	**Date/Signature: _____**

The following is furthermore to be simulated and documented:

Do the parameter settings remain following a power failure?	☐ yes	☐ no	
Compliance	☐ yes	☐ no	**Date/Signature: _____**

f) Training / Schooling

Name of trained employee	Training			Hand signal	
	Trained by	Qualification	Date	Trainer	Trainee

Note:

The Installation Qualification is to be considered passed only when all questions can be answered with a ‘yes’ and when the required verification exists.

5.3 Appendix C: Checklist Operational Qualification (OQ), Page 1 of 1

Criteria			**Lower limit (LL)**		**Upper limit (UL)**	
1. Reference-Temperature (according to Packaging manufacturer =M*)			LLM		ULM	
2. Actual-Temperature during the test (read off)			LL		UL	
3. Condition			LL >= LLM		UL <= ULM	
4. Compliance with conditions in line 3	☐ yes	☐ no				
Peelability (visual test)			☐ yes	☐ no	☐ yes	☐ no
Quality properties			**Compliance**		**Compliance**	
Intact seal for a specified seal width			☐ yes	☐ no	☐ yes	☐ no
Verified by						
No channels or open seals.			☐ yes	☐ no	☐ yes	☐ no
Verified by						
No punctures or tears			☐ yes	☐ no	☐ yes	☐ no
Verified by						
No material delamination or separation			☐ yes	☐ no	☐ yes	☐ no
Verified by						
Temperature (T) determined for the PQ **(Average between lower limit and upper limit is the Actual-Temperature during the test)**			T = _____			

* In case of use of special materials (e.g. Tyvek) the limit values must, where necessary, be determined through test sealing (DIN 58953-7).

5.4 Appendix D: Checklist Performance Qualification (PQ), page 1 of 1

Temperature defined for the sealing process (carried forward from OQ Checklist)	T=_____			
Actual-Temperature for the operational qualification (amount carried forward from OQ Checklist)	LL:		UL:	
Switch-off tolerance in Degrees Celsius according to DIN 58953-7 (according to sealing device manufacturer's specifications, as a general rule + /- 5 °C)	A =_____			
Resulting lower and upper value	T- A	=	T+ A	=
Conditions	**T- A >= LL**		**T+ A<= UL**	
Compliance with conditions	☐ yes	☐ no	☐ yes	☐ no

Criteria	**Sterilization-cycle A**		**Sterilization-cycle B**		**Sterilization-cycle C**	
Date/time of sterilization						
Sterilization protocol available and correct operational procedure confirmed	☐ yes	☐ no	☐ yes	☐ no	☐ yes	☐ no
Sealing parameters						
Temperature						
Contact pressure						
Time /Speed						
Seal seam resistance						
Free end supported	☐ yes	☐ no	☐ yes	☐ no	☐ yes	☐ no
Maximum resistance						
Sample 1	A1:		B1:		C1:	
Sample 2	A2:		B2:		C2:	
Sample 3	A3:		B3:		C3:	
Sample 4	A4:		B4:		C4:	
Sample 5	A5:		B5:		C5:	
Test Passed **(when all values >= 1,5 N/15mm)**	☐ yes	☐ no	☐ yes	☐ no	☐ yes	☐ no
Verified by Institute, Company, etc, name						

5.5 Appendix E: Example for determining the scale of the process validation for each sealing device

Example from a medical practice

A Central Sterilization and Supply Department (CSSD) has 2 sealing devices, 3 different steam sterilization programs are in use, 1 EO-sterilizer and a "plasma sterilizer" each with a program.

The materials were assigned as follows:

Sealing device 1	**Steam**			**NTDF**	**ETO**	**H_2O_2**
	134 °C/5 min	134 °C/18 min	121 °C/20 min			
Material A Pouches EN 868-5	X	**X***	X		X	
Material B Gusseted pouches EN 868-5	X	**X***	X		X	
Material C Tyvek®						
Material D Paper bag EN 868-4	**X***					
Sealing device 2	**Steam**			**NTDF**	**ETO**	**H_2O_2**
	134 °C/5 min	134 °C/18 min	121 °C/20 min			
Material A Pouches EN 868-5						
Material B Gusseted pouches EN 868-5						
Material C Tyvek®						**X***
Material D Paper bag EN 868-4						

The resulting 10 combinations in this table can be reduced, by taking into account only the maximum stress on the material ("worst-case" scenario with documented explanation, in this example it is for material A and B: 134°C/18 min). These combinations are marked with an X* in the table. From this it follows that in this example a total of 4 Performance Qualifications (PQ) were carried out. A further reduction can be achieved by conscious selection of sterile barrier systems (e.g. larger pouches instead of gusseted pouches, transparent pouches instead of paper bags). In this example, the 4 performance qualifications would be reduced to 2.