D.2 Validation plan checklist: Heat Sealing Process Preformed Sterile Barrier Systems (PSBS: Pouches, Reels, etc.)

☐ **Validation** ☐ **Revalidation**

a) Responsibilities

Name of facility	
Location	
Validation participants	
Person responsible for the entire validation	
File location	

b) Description of the assembled sterile barrier systems

Contents of sterile barrier system	
Is this the worst-case scenario? If so, describe rationale:	
Number of sterile barrier systems assembled	
Approved procedure or SOP used to assemble	
Was internal organizing tray, tip protector for sharp medical devices etc. to support the medical device and protect the sterile barrier system used?	☐ yes ☐ no
If internal support/protection was used, describe:	

c) Description of sterilization processes

Manufacturer of sterilizer and model number			
Serial number of sterilizer			
Is this a contract sterilizer?	☐ yes ☐ no		
Sterilization cycle Attach printout if available	☐ Steam (highest temp./longest time) ☐ Ethylene oxide (EO) ☐ other _____	☐ Plasma ☐ Low temperature steam formaldehyde (LTSF)	
Is this the worst-case cycle?	☐ yes	☐ no	cycle parameters: _____
Approved SOP or loading procedure used			
Process validated?	☐ yes	☐ no	
Validated by:			
Date of last validation:			
Date of next validation:			

d) Description of pouches and reels (preformed sterile barrier system)

Manufacturer of preformed sterile barrier systems			
Type/Grade			
Supplier contact information: Name: Address: Phone:			
Is supplier also the manufacturer of the pouches and /or reels?	□ yes	□ no	
Does manufacturer provide documented evidence of a quality management system (e.g. QM certificate, registration, etc.)	□ yes	□ no	
Has manufacturer validated their pouch/reel manufacturing process?	□ yes	□ no	□ verification
Does supplier provide documentation demonstrating they have fulfilled the requirements of ISO 11607-1?	□ yes	□ no	□ verification
If applicable, does supplier provide documentation of fulfilling requirements of regional product specific document (e.g. EN 868-5)?	□ yes	□ no	□ verification
Sealing temperature range (in °C)*?	from _____to _____ Data from:_____ □ Verification available		
Sterilization process to be used:			
Is the preformed sterile barrier system compatible to the sterilization process?	□ yes	□ no	
Is the storage and handling of preformed sterile barrier systems in the hospital in accordance with regional/ national/local standards or requirements?	□ yes	□ no	□ not available

e) Description of the sealing device

Sealing device manufacturer			
Type of sealing device			
Serial number (SN)			
Does temperature switch-off tolerance exist? [e.g. according to DIN 58953-7 (±5 °C)] Enter tolerance.	□ yes	□ no	Tolerance
Supplier of the sealing device.			

Supplier contact information: Name: Address: Phone:			
Date of last calibration.			
Does manufacturer provide documentation demonstrating that the equipment is capable of meeting the requirements of ISO 11607-2?	□ yes	□ no	□ verification
Are manufacturer's directions for use available?	□ yes	□no	
When were they updated and where are they archived?			

f) Description of the protective packaging as well as handling, distribution and storage challenges

Protective packaging — Describe type of protective packaging — Applied after item is cool — Clearly labelled as protective packaging — Transport trays	 □ yes □ yes □ yes	 □ no □ no □ no
Description of handling, distribution and storage Has documentation been completed, e.g. see D.5?	□ yes	□ no
How often are sterile items moved or handled before arriving at their final point of use? — Number of events with risk of loss of integrity?		
Consider worst-case for Performance Qualification of the packaging system (combination of protective packaging and sterile barrier system) — What is the worst-case? — What is the rational for selection?		

g) Acceptance criteria — define method and acceptance criteria

Attribute	Method for evaluating	Acceptance criteria	
Seal integrity		Intact and continued seal Meets specified width No channel openings No wrinkles, creases or bubbles	
Package integrity		No punctures, tears, breaks	
Seal strength			
Aseptic presentation		Able to open without damage or contamination of the contents	
Peel ability	**Peelable without** material rupture, delamination, separation or degradation	□ yes	□ no
Other			

h) Qualification steps

Installation Qualification (IQ)	□ executed	
	□ previously executed in the validation dated: _____	
	□ pass	□ fail
	Date/Signature:	
Operational Qualification (OQ)	□ executed	
	□ date previously executed in the validation on _____	
Was acceptance criteria defined in (g) above met? Attach results	□ pass	□ fail
	Date/Signature:	
Performance Qualification (PQ)	□ executed	
Was acceptance criteria defined in (g) above met? Attach results	□ pass	□ fail
	Date/Signature:	

i) Summary approval of the validation

□ All parts of the validation passed, results attached.

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

_____

Follow-up or corrective actions to be taken:

_____

□ Follow-up actions were determined and documented, results attached

Date of next scheduled review _____

_____
Signature

_____ _____
Place, Date Name in block print

D.3 Validation plan checklist: wrapping process

□ **Validation** □ **Revalidation**

a) Responsibilities

Name of facility	
Location	
Validation participants	
Person responsible for the entire validation	
File location	

b) Description of sterilization wrap

Manufacturer of sterilization wrap			
Type/Grade	□ Crepe paper □ Nonwoven □ Textile □ Plain paper	□ Others If others, specify:	

Supplier contact information: Name: Address: Phone:			
Is supplier the manufacturer of the wrap?	□ yes □ no		
Does manufacturer provide documented evidence of a quality management system (e.g. QM certificate, registration, etc.)	□ yes	□ no	
Does supplier provide documentation demonstrating they have fulfilled the requirements of ISO 11607-1?	□ yes	□ no	□ verification
If applicable, does manufacturer provide documentation of fulfilling requirements of regional product specific document (e.g. EN 868-2)?	□ yes	□ no	□ verification
Sterilization process to be used:			
Is the sterile barrier system compatible with the sterilization process?	□ yes	□ no	
Is the storage and handling of wrap in the hospital in accordance with regional/ national/local standards or requirements?	□ yes	□ no	

c) Description of the wrapping closure system

Manufacturer of closure		
Type/Grade/lot number	□ Adhesive tape	□ Label

	□Indicator tape	□ Others If others, specify:
Lot number of closure system (tape)?		
Supplier contact information: Name: Address: Phone:		
Is supplier the manufacturer of the closure system?		
Does manufacturer provide documented evidence of a quality management system (e.g. QM certificate, registration, etc.)	□ yes □no	
Does manufacturer provide documentation demonstrating they have fulfilled the requirements of ISO 11607-1?	□ yes □ no	□ verification
If applicable, does manufacturer provide documentation of fulfilling requirements of regional product specific document?	□ yes □ no	□ verification
Sterilization process to be used:		

d) Description of assembled sterile barrier systems (wrapping)

Contents of sterile barrier system	
Is this worst-case configuration? If so describe the rationale.	
Number of sterile barrier systems assembled	
Approved procedure or SOP used to assemble	
Was internal organizing tray, tip protector for sharp medical devices, corner protectors between tray and wrap, tray liner etc. to support the medical device and protect the sterile barrier system used?	□ yes □ no
If internal support/protection was used, describe, like:	

e) Description of sterilization processes

Manufacturer of sterilizer and model number		
Serial number of sterilizer		
Is this a contract sterilizer?	□yes	□ no
Sterilization cycle Attach printout if available	□ Steam (highest temp./longest time) □ Ethylene oxide (EO) □ other _____	□ Plasma □ LTSF (low temperature steam formaldehyde)

Is this the worst-case cycle?	□ yes	□ no	cycle parameters: _____
Approved SOP or loading procedure used			
Process validated?	□ yes	□ no	
Validated by:			
Date of last validation:			
Date of next validation:			

f) Description of protective packaging as well as handling, transportation, distribution and storage challenges

Protective Packaging — Describe type of protective packaging — Applied before sterilization — Applied after item is cool — Clearly labelled as protective packaging — Dust cover — Transport trays	 □ yes □ yes □ yes □ yes □ yes	 □ no □ no □ no □ no □ no
Description of handling, distribution and storage Has documentation been completed, e.g. see D.5?	□ yes	□ no
How often are sterile items moved or handled before arriving at their final point of use? — Number of events with risk of loss of integrity?		
Consider worst-case for Performance Qualification of the packaging system (combination of protective packaging and sterile barrier system) — What is the worst-case? — What is the rational for selection?		

g) Acceptance criteria — define method and acceptance criteria

Attribute	Method for evaluating	Acceptance criteria
Closure integrity		continuous, no opening or breaches, no channels
Package integrity		No punctures, tears, breaks,
Aseptic presentation		able to open without damage or contamination of the contents
Assembly (folds, etc.) according to documented procedure/assembly instructions		The opened sterile barrier system conforms to the documented procedure/assembly instructions
Packaging configuration processed in the defined cycle		Have all sterilization parameters for the defined packaging configuration been met [see 3.2.3 b)]?

Other		

h) Qualification steps

Installation Qualification (IQ)	□ executed	
	□ previously executed in the validation dated:_____	
	□ pass	□ fail
	Date/Signature:	
Operational Qualification (OQ)	□ executed	
	□ date previously executed in the validation on _____	
Was acceptance criteria defined in (f) above met? Attach results	□ pass	□ fail
	Date/Signature:	
Performance Qualification (PQ)	□ executed	
Was acceptance criteria defined in (f) above met? Attach results	□ pass	□ fail
	Date/Signature:	

i) Summary approval of the validation

☐ All parts of the validation passed, results attached.

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

_____

Follow-up or corrective actions to be taken

_____

☐ Follow-up actions were determined and documented, results attached

Date of next scheduled review _____

_____
Signature

_____
Place, Date

_____
Name in block print

D.4 Validation plan checklist: container process

□ **Validation** □ **Revalidation**

a) Responsibilities

Name of facility	
Location	
Validation participants	
Person responsible for the entire validation	
File location	

b) Description of the rigid container

Manufacturer of rigid container				
Type/Grade	gasket	single use filter	re-usable filter	other
Supplier contact information: Name: Address: Phone:				
Is supplier the manufacturer of the rigid container?	□ yes	□ no		
Does manufacturer provide documented evidence of a quality management system (e.g. QM certificate, registration, etc.)	□ yes	□ no		
Does supplier provide documentation demonstrating they have fulfilled the requirements of ISO 11607-1?	□ yes	□ no	□ verification	
If applicable, does supplier provide documentation of fulfilling requirements of EN 868-8?	□yes	□ no	□ verification	
Is the filter used provided or recommended by the manufacturer of the container?	□ yes	□ no	□ verification	
If not, did the filter supplier provide documented evidence of its efficacy and compatibility with the specific container and sterilization process that was used?	□ yes	□ no	□ verification	
Sterilization process to be used:				
Is the sterile barrier system compatible to the sterilization process?	□ yes	□ no		
Is the storage and handling of containers in the hospital in accordance with regional/ national/local standards or requirements?	□ yes	□ no		

c) Description of the tamper evident system used to demonstrate the closure integrity

Manufacturer tamper evident system			
Type/Grade			
Supplier contact information: Name: Address: Phone:			
Is supplier the manufacturer of the tamper evident system?	□ yes		□ no
Does the tamper evident system provide the following characteristics? — provide visual indication of tampering	□ yes		□ no
— hinders opening of the container and provides visual indication or tampering (physically blocks opening of the container)	□ yes		□ no
— indicate that the lid has been physically secured to the bottom part of the container since sterilization	□ yes		□ no
If a single use tamper evident system is used is there a lot number?	□ yes LOT-No.:		□ no
Does manufacturer provide documented evidence of a quality management system (e.g. QM certificate, registration, etc.)	□ yes	□ no	
Does supplier provide documentation demonstrating they have fulfilled the requirements of ISO 11607-1?	□ yes	□ no	□ verification
Sterilization process to be used:			
Is the closure system compatible to the sterilization process?	□ yes	□ no	

d) Description of assembled container

Contents of sterile barrier system		
Is additional packaging used within the container?	□ yes	□ no
Is the additional packaging a sterile barrier system?	□ yes	□ no
Is this the worst-case configuration, if so describe the rationale		
Number of sterile barrier systems assembled		
Procedure or SOP used to assemble		
Was internal organizing tray, tip protector for sharp medical devices etc. to support the medical device and protect the sterile barrier system used?	□ yes	□ no
If internal support/protection was used, describe:		

e) Description of sterilization processes

Manufacturer of sterilizer and model number			
Serial number of sterilizer			
Is this a contract sterilizer?	□ yes	□ no	
Sterilization cycle Attach print-out if available	□ Steam (highest temp./longest time) □ Ethylene oxide (EO) □ other _____		□ Plasma □ Formaldehyde (FO)
Is this the worst-case cycle?	□ yes	□ no	cycle parameters: _____
SOP or loading procedure used			
Process validated?	□ yes	□ no	
Validated by:			
Date of last validation:			
Date of next validation:			

f) Description of the handling, distribution and storage challenges

Has documentation been completed, e.g. see D.5?	□ yes	□ no
How often are sterile items moved or handled before arriving at their final point of use? — Number of events with risk of loss of integrity?		
Consider worst-case for Performance Qualification of the packaging system (combination of protective packaging and sterile barrier system) — What is the worst-case? — What is the rational for selection?		