### 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<br>Attach printout if available | ☐ Steam (highest temp./ longest time)<br>☐ Ethylene oxide (EO)<br>☐ other<br>_____ | ☐ Plasma<br>☐ Low temperature steam formaldehyde (LTSF) | |
| Is this the worst-case cycle? | ☐ yes | ☐ no | cycle parameters:<br>_____ |
| 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:<br>Name:<br>Address:<br>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 _____<br>Data from:_____<br>☐ 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:<br>Name:<br>Address:<br>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 | ☐ yes | ☐ no |
| — Applied after item is cool | ☐ yes | ☐ no |
| — Clearly labelled as protective packaging | ☐ yes | ☐ no |
| — Transport trays | | |
| **Description of handling, distribution and storage**<br>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?<br>— 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)<br>— What is the worst-case?<br>— 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<br>Meets specified width<br>No channel openings<br>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:<br>_____ | |
| | ☐ pass | ☐ fail |
| | Date/Signature: | |
| **Operational Qualification (OQ)** | ☐ executed | |
| | ☐ date previously executed in the validation on<br>_____ | |
| Was acceptance criteria defined in (g) above met?<br>Attach results | ☐ pass | ☐ fail |
| | Date/Signature: | |
| **Performance Qualification (PQ)** | ☐ executed | |
| Was acceptance criteria defined in (g) above met?<br>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<br>☐ Nonwoven<br>☐ Textile<br>☐ Plain paper | ☐ Others<br>If others, specify: | |
| Supplier contact information:<br>Name:<br>Address:<br>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<br>If others, specify: |
| Lot number of closure system (tape)? | | | |
| Supplier contact information:<br>Name:<br>Address:<br>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<br>Attach printout if available | ☐ Steam (highest temp./ longest time)<br>☐ Ethylene oxide (EO)<br>☐ other<br>_____ | | ☐ Plasma<br>☐ LTSF (low temperature steam formaldehyde) |
| Is this the worst-case cycle? | ☐ yes | ☐ no | cycle parameters:<br>_____ |
| 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** | ☐ yes | ☐ no |
| — Describe type of protective packaging | ☐ yes | ☐ no |
| — Applied before sterilization | ☐ yes | ☐ no |
| — Applied after item is cool | ☐ yes | ☐ no |
| — Clearly labelled as protective packaging | ☐ yes | ☐ no |
| — Dust cover | | |
| — Transport trays | | |
| **Description of handling, distribution and storage**<br>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?<br>— 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)<br>— What is the worst-case?<br>— 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 |

| Attribute | Method for evaluating | Acceptance criteria |
|---|---|---|
| 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? | ☐ pass | ☐ fail |
| Attach results | Date/Signature: | |
| **Performance Qualification (PQ)** | ☐ executed | |
| Was acceptance criteria defined in (f) above met? | ☐ pass | ☐ fail |
| Attach results | 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:<br>Name:<br>Address:<br>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:<br>Name:<br>Address:<br>Phone: | | | |
| Is supplier the manufacturer of the tamper evident system? | ☐ yes | | ☐ no |
| Does the tamper evident system provide the following characteristics?<br>— provide visual indication of tampering<br>— hinders opening of the container and provides visual indication or tampering (physically blocks opening of the container)<br>— indicate that the lid has been physically secured to the bottom part of the container since sterilization | ☐ yes<br>☐ yes<br>☐ yes | | ☐ no<br>☐ no<br>☐ no |
| If a single use tamper evident system is used is there a lot number? | ☐ yes<br>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<br>Attach print-out if available | ☐ Steam (highest temp./ longest time)<br>☐ Ethylene oxide (EO)<br>☐ other _____ | ☐ Plasma<br>☐ 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?<br>— 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)<br>— What is the worst-case?<br>— What is the rational for selection? | | |

### g) Acceptance criteria- define method and acceptance criteria

| Attribute | Method for evaluating | Acceptance criteria |
|---|---|---|
| Latching mechanism and Closure continuity/integrity | | Closure continuity/integrity maintained without closure rupture |
| Filter/valve integrity | | No punctures, tears, channels, damage |
| Gasket integrity | | No damage (see 3.3.2.9.2) |
| Aseptic presentation | | able to open without damage or contamination of the contents |
| 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?<br>Attach results | ☐ pass | ☐ fail |
| | Date/Signature: | |
| **Performance Qualification (PQ)** | ☐ executed | |
| Was acceptance criteria defined in (f) above met?<br>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.5 Handling and distribution checklist: handling, distribution and storage

The following checklist should help to make the choice of the sterile barrier system used.

**Anticipated challenges that effect integrity of sterile barrier systems**

Does the manufacturer provide recommendations for the conditions of handling, storage and distribution?

| | | |
|---|---|---|
| — Temperature | ☐ yes | ☐ no |
| — Relative humidity | ☐ yes | ☐ no |
| — Handling requirements | ☐ yes | ☐ no |
| — Restrictions on agitation | ☐ yes | ☐ no |
| — Bumps and other movement | ☐ yes | ☐ no |

**Description of handling and staff attire**

| | | |
|---|---|---|
| Is there an education program for staff who handles sterile barrier systems? | ☐ yes<br>if yes describe | ☐ no |
| Is there a hand hygiene protocol? | ☐ yes<br>if yes describe | ☐ no |
| Is there a dress code? | ☐ yes<br>if yes describe | ☐ no |
| Is the number of times a sterile barrier system is handled from point of sterilization to point of use known? | ☐ yes<br>if yes describe | ☐ no |

**Description of distribution/transport means**

**On site transportation**

| | | |
|---|---|---|
| — Can the clean and/or sterile medical devices be transported and stored separately from soiled medical devices? | ☐ yes | ☐ no |
| — Are these sterile medical devices covered or enclosed during transport? | ☐ yes | ☐ no |