

# Scottish Health Technical Memorandum 01-01

Decontamination of medical devices in a Central  
Decontamination Unit

Part F: Inspect, Assemble and Package

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# 1. Introduction

- 1.1 Scottish Health Technical Memorandum (SHTM) 01-01 Part F offers best practice guidance on 'Inspect, Assemble and Package' of medical devices in a CDU. Refer to SHTM 01-01 Part A on 'Management' which includes a glossary.
- 1.2 Part F is intended as a guide for management, for technical personnel with appropriate training and experience, and also for users responsible for the day-to-day management of decontamination processes. It will also be of interest to microbiologists, infection control officers, planners, supplies officers and others in both the public and private sectors.

## Scope of SHTM 01-01 Part F

- 1.3 This guidance on 'Inspect, Assemble and Package' covers inspection, assembly and package processes (see [Figure 1](#)) for medical devices within the Central Decontamination Unit. Packaging for medical equipment which has been cleaned, disinfected and serviced ready for return to use without sterilization is not included in this guidance.

**Note 1:** For the purposes of this series “**medical device**” is taken to mean as applicable both a reusable medical device and a single use medical device that is supplied non sterile to the CDU for processing once prior to use. The term medical device as used in the SHTM 01-01 series only applies to those processed through a CDU.

**Note 2:** Elements of the medical device decontamination process that are applicable to the clinical environment can be found in the SHTM 01-01 supplement guidance GUID 5017 'Guidance for service users'. The guidance indicated that surgical instruments were medical devices.

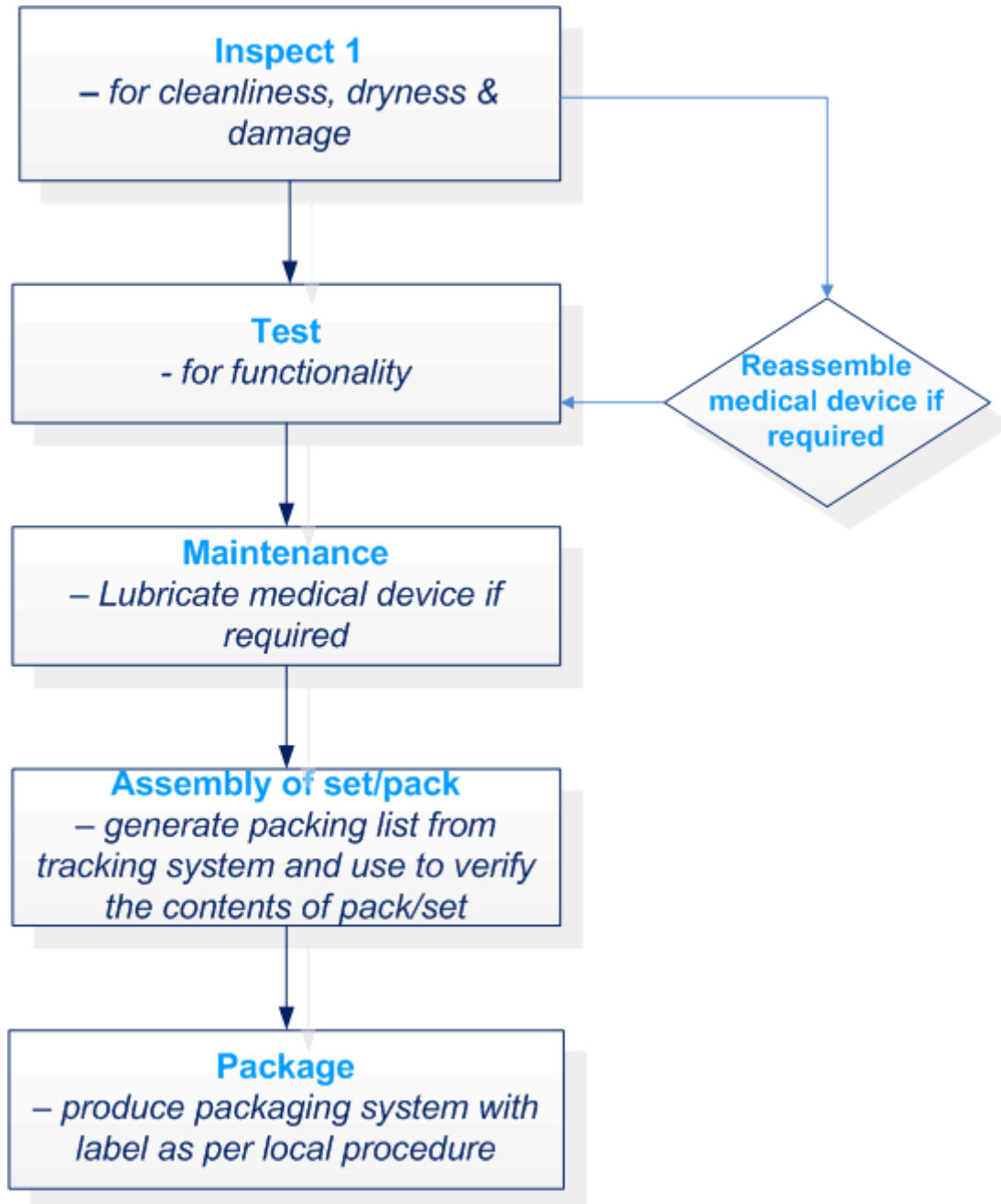


Figure 1: Elements of the inspect, assemble and package process

### Operational policy in SHPN 13 Part 1

1.4 The inspect, assemble and package activities are undertaken in a controlled environment, the IAP Room within a Central Decontamination Unit. The planning note SHPN 13 Part 1: 2011 sets requirements for the IAP Room. The operational policy on Inspection, assembly and packing in SHPN 13 Part 1: 2011 indicates the following.

- the IAP Room will receive goods from the Wash Room and materials from the IAP Materials Transfer Room. These will then be inspected and assembled onto trays and into procedure packs in preparation for sterilization. Adventitious contamination should be minimised by all practicable means;

- the IAP Room should be an ISO Class 8 cleanroom in the 'operational' occupancy state with a pressure differential higher than adjoining areas. Cleanroom discipline should be followed by all staff;
- a room directly connected to the IAP Room, i.e. the IAP Gowning Room, should be an ISO Class 9 cleanroom in the 'operational' occupancy state. The room should be designated for staff changing into cleanroom clothing before they enter the IAP Room;
- controlled entry and exit of personnel and materials via separate dedicated air locks/transfer hatches should be incorporated to maintain the integrity of the IAP Room. Staff shall not be able to leave or enter the IAP Room other than via the IAP Room: Gowning Room, unless in an emergency. The Fire Safety Officer should be consulted at the design stage to specify suitable evacuation procedures;
- raw materials enter the IAP Room via the IAP Materials Transfer Room. Trolleys shall not pass into or out of the IAP Room unless the procedure has been validated to ensure acceptable levels of contamination are not exceeded;
- all wet processes including hand-washing should take place outwith the IAP Room. This will help to minimise the contamination of medical devices during production. Inspection activities should be approved and minimize the generation of contamination within the room.

### Requirements for compliant Central Decontamination Units

- 1.5 Within the 2016 HFS publication GUID 5014 'Requirements for compliant CDUs' under Appendix 1 table 1 Equipment it states that installation, validation and periodic testing of equipment such as heat sealers is required as per the latest standards and guidance. The standards being EN ISO 11607-1 & 2: 2017 and the guidance being the technical specification CEN ISO/TS 16775: 2014.
- 1.6 The process section in table 1 Appendix 1 of GUID 5014 states that production of sterile products should be compliant with the latest standard EN 556-1: 2001 and the pre-sterilization packaging standards EN ISO 11607-1 & 2. The process section also states that labelling should be in accordance with the Medical Device Directive 93/42/EEC. This directive will be repealed as per article 122 of the new European regulation 2017/745 on medical devices (see the note below).

**Note: Regulation (EU) 2017/745 of the European parliament and of the council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. The regulation was published in the Official Journal of the European Union journal L117 of 5th May 2017.**

## 2. Inspect and assemble

### Introduction

- 2.1 Standards for the production of sterile products recognise the importance of quality assurance and quality control. Inspection is a key component of the quality process. Washed and disinfected medical devices received from the wash room, together with raw materials from the materials transfer room, will need to be inspected, assembled and then packed for sterilization.
- 2.2 EN ISO 17664: 2017 – ‘Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices’, recommends that relevant information shall be provided within the instructions for use if inspection, functionality testing, maintenance (including replacement of parts) or calibration of a medical device is required during or after processing to ensure its proper function and safe use.
- 2.3 Instructions for use should include the following information where applicable:
- the method(s) and performance criteria for inspecting the device. This should include device functionality including its impact on patient safety and safe use;
  - the instructions for assembly/re-assembly of the medical device;
  - the method that should be used for adjustment and/or calibration of the medical device;
  - the type, amount and method of application of any lubricant required;
  - a description of any special tools required to maintain the medical device.
- 2.4 CDUs should follow these instructions for use to ensure the medical device remains safe to use.

### Inspection and testing of medical devices

- 2.5 All cleaned and disinfected medical devices should be inspected for cleanliness, dryness and signs of damage on entry into the inspection and assembly area. This includes devices being carefully examined for contaminants (using task lighting and magnification where appropriate). Where advised by the medical device manufacturer’s instructions for use, medical devices should be lubricated. Prior to assembly and subsequent sterilization, all cleaned and disinfected devices should then be tested and/or inspected for functionality and damage.
- 2.6 The inspection, maintenance, testing and assembly of medical devices and packs must be carried out by suitably trained staff in accordance with the manufacturer’s instructions for use and local CDU policy. Where practical, the inspection and function-testing of devices should not be carried out by the same staff responsible for cleaning the devices. These staff members have a responsibility for ensuring the item is thoroughly cleaned and fit for reuse. Worn or damaged medical device should be quarantined pending repair or replacement. Quarantine areas should be lockable where possible to prevent unauthorised access.

- 2.7 The importance of inspecting each medical device cannot be over-emphasised. Some medical devices have a defined limited number of uses. A visual check (using task lighting and magnification where appropriate) for cleanliness and dryness should be made. All non-conforming product – that is, dirty, wet or stained to an unacceptable level – should be rejected and returned to the wash area for further cleaning. This may be an additional manual cleaning step, followed by a second automated wash process (where this process is available and the device is compatible) before continuing through to re-inspection, packaging and sterilization. A root cause analysis should be carried out to determine the reasons behind any non-conforming product. A record of returns should be noted.
- 2.8 The condition of the medical device has a significant effect on how adequately it can be cleaned. Medical devices that are subjected to rough handling (despite being made of stainless steel!) will develop scratches and roughened surfaces, which will harbour dirt.
- 2.9 Medical devices that have an outer insulation coating, for example diathermy forceps, require close inspection to ensure that the insulation remains intact. Damaged surfaces will not only allow dirt and bacteria to collect, but can also be potentially dangerous for both staff and patients. If inspection reveals damage, record and action according to in house procedure.
- 2.10 As part of the decontamination process, all medical devices should be subject to function testing following cleaning and inspection to ensure that they will perform the tasks for which they are designed. Consult the medical device manufacturer's instructions for use. It is difficult to test medical devices instruments to mimic their actual use; however, some basic tests can be undertaken to ensure that:
- there is free movement of all parts and that joints do not stick;
  - ratchets close easily and hold firm;
  - the edges of clamping medical devices meet with no overlap and that teeth mesh together;
  - scissor edges meet to the tip and move freely across each other with no overlap or burrs (rough edges);
  - all screws on jointed medical devices are tight and have not become loose during the cleaning process;
  - there is compatibility of medical devices used together;
  - sharp points are protected where possible with covers ensuring steam penetration is possible;
  - there is an inspection of cables' outer sleeves and connectors noting that this is not an electrical integrity check;
  - lumens are checked for cleanliness and are free of debris.
- 2.11 Where practicable, functionality testing should be carried out by a person not responsible for cleaning the item.
- 2.12 Small micro-surgery medical devices and those with small interstices and detailed profiles may require the use of a magnifier and higher levels of illumination than is

available for general room lighting. Lenses of 3 to 6 dioptries are normally sufficient. SHPN 13 Part 1: 2011 in Room Data Sheet 17 defines light levels at the work station height.

- 2.13 The extent to which testing is necessary depends on the nature of the device, the nature of the procedure for which it is being used and the ease with which the clinician can determine from its in-use performance that the device should be replaced / repaired before the defect becomes critical.
- 2.14 Function tests of complex, multipart medical devices should be carried out on the fully assembled medical device. The item should be taken apart again for sterilization after successful testing if recommended in the manufacturer's instructions for use. Assembling and disassembling must be undertaken in accordance with the manufacturer's instructions for use.
- 2.15 Before sterilization, surgical motors and their accessories may require a functional test, in accordance with the manufacturer's instructions for use. Compressed air components may also require a leak test and be visually inspected for potential defects, especially the compressed air hoses and motors. To check the air intake duct, it is often necessary to connect the air hose to the compressed air connector. To check the air discharge duct, the compressed air motor must also be connected to the compressed air hose. This activity should be carried out in a specialist cabinet. Refer to the SHPN13 Part 1: 2011 Room Data Sheet 17 for the IAP Room and the standard EN 14175-2: 2003 on fume cupboards.
- 2.16 Rigid endoscope glass lenses, optical fibre cables and camera heads may require particular attention. Optical fibre cables and endoscopes should be checked for fibre breakage. This can be undertaken by holding the distal end against a light source and looking into the cable at the other end (the connector side of optic). Fibre breakage is indicated by black spots in the waveguide. If more than 30% of the fibres are broken, the light output at the distal end is unlikely to be adequate. Specialist light lead test equipment is now available which can objectively test the lead. The machine check is done after the light check.
- 2.17 Gaskets and sealing rings of medical devices should be checked for integrity before each sterilization cycle. If damaged, they must be replaced. Cannulas should be checked for damage and distortion.
- 2.18 Records should be kept indicating who was responsible for inspecting, maintaining and testing the devices. This may be undertaken by different staff members and if so, all involved should be recorded. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from a skills register.
- 2.19 Devices that fail inspection for cleanliness or functionality should be segregated from other devices. As stated previously, these should be redirected for further cleaning.

**Note:** The "Red Book", Reprocessing of Instruments to Retain Value, 10th anniversary edition 2016, published by the Instrument Reprocessing Working Group (a working group of instrument manufacturers, detergent suppliers and washer-disinfector manufacturers) provides useful information on inspection and functionality testing of surgical instruments in addition to advice on corrosion.



## Assembly of medical devices

- 2.20 Prior to packaging, some medical devices disassembled for cleaning and disinfection may be reassembled after inspection. Many medical devices will then be assembled into trays/baskets/containers to form instrument sets or procedure packs. Medical devices may need to be disassembled again for sterilization. Be aware of weight restrictions that impacts on the packaging system and manual handling requirements.
- 2.21 There should be detailed assembly instructions for each disassembled device and each set. Pictures of the layout and content of each set may be useful.
- 2.22 Each set should have an associated list of the contents (a specification) which includes details of the logical packing order as agreed with service users. The list should have appropriate fields for completion of pre and post operative checks by the service users. These set checklists (often called tray build sheets, tray lists or packing lists) should be version controlled within the Quality Management System.
- 2.23 Records should be kept indicating who was responsible for assembling the device and the set. Evidence that the person carrying out the work is trained and capable to do so should be verifiable from a skills register. The records may be electronic in nature.
- 2.24 EN ISO 17664: 2017 recommends that relevant information shall be provided within the instructions for use for re-assembly of the individual medical device if it requires disassembly for processing.

**Note:**

## Quality improvement in inspection and assembly

Inspection, functionality testing and assembly of medical device and sets is one area of decontamination where human factors can greatly influence the perception of a service received by clinicians and patient safety as it is still a manual, labour intensive process.

If cleaning failures, instrument faults and incorrect assembly can be detected before sterilization, the incidence of errors associated with surgical sets and non-conformities identified by users of the sets is reduced. Implementing a surgical set quality improvement process fits perfectly into any quality management system and risk management process.

There are many, well publicised quality improvement tools and lean management methodologies available. Many can bring benefits to CDU production and should be considered. However one principle that can be applied to the inspection and assembly process relatively easily is work simplification and process standardization:

*Examples:*

- 1) *Provide all needed materials within the technician's reach;*
- 2) *Eliminate unnecessary materials from medical device sets;*
- 3) *Remove unneeded medical devices from the set to reduce the set size and simplify the assembly;*
- 4) *Provide accurate build sheets, IT solutions, or pictures to assist in the assembly process;*
- 5) *Bring medical devices to the assembler and minimise walking and transporting;*
- 6) *Ensure extra medical devices are readily available to replace missing ones in a controlled manner;*
- 7) *Develop clear procedures available to handle non-conforming situations;*
- 8) *Determine what best practice looks like and involve those doing the work to identify it;*
- 9) *Standardise to best practice;*
- 10) *Document best practice in procedures and work instructions.*

**Lubrication of medical devices**

2.25

Lubricants may be necessary for the correct functioning of the device yet can often compromise the cleaning, disinfection and sterilization processes if not carried out with the correct materials and at the correct stage of the process. Consult the medical device manufacturer's instructions for use on this matter.

- 2.26 Lubricants should generally be applied after cleaning and disinfection. Washer-disinfectors will often remove any lubrication added and by applying a lubricant prior to this process there is a risk of compromising the quality of the final rinse water.
- 2.27 In-process medical device lubricants which deposit a lubricant film on all surfaces of the medical device should only be used on specific cycles for specific devices and only if the lubricant has been demonstrated to be compatible with any subsequent sterilization process. Examples of this include purpose designed washers for turbine instruments. However, the addition of oil-based compounds to the cleaning process is wrong in principle. They deliberately cause contamination over the entire cleaned surface. Follow the manufacturer's instructions for use.
- 2.28 Mineral oils have poor biocompatibility and may inhibit the penetration of steam or sterilant gases on terminally sterilized product. The automatic dosing of lubricants in washer-disinfectors is generally contra-indicated. The type, quantity and method of application of the lubricant should be in accordance with the manufacturer's instructions for use.

**Note:** The "Red Book", Reprocessing of Instruments to Retain Value document 2016 states:

"Maintenance and care measures are usually carried out prior to the functional check. Maintenance or care means **targeted** application of a lubricant milk to the joints, hinges, locks, threads or friction surfaces of instruments such as clamps, scissors or punches, **after** they have been carefully cleaned and disinfected."

## 3. Packaging system

### Introduction

- 3.1 This section discusses the factors which should be considered in the selection and use of packaging systems for terminally sterilized medical devices that is, those devices which are sterilized in their packaging.

**Note:** The following terms are used extensively throughout this section and are aligned with those used in 'Theatres and CDU Guidance: Management of reusable surgical instruments during transportation, storage and after clinical use' – GUID 5010: 2014.

**Packaging system:** combination of the sterile barrier system and protective packaging. [EN 11607-1: 2017]

**Protective packaging:** configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use. [EN 11607-1: 2017]

**Sterile barrier system:** minimum package that prevents ingress of microorganisms and allows aseptic presentation of the product at the point of use. [EN 11607-1: 2017]

**Note:** Standard EN ISO 11607-1: 2017 is titled 'Packaging for terminally sterilized devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems'.

This establishes requirements for evaluation of usability for aseptic presentation and requirements for inspection of sterile barrier system integrity prior to use.

It defines aseptic presentation as the transfer of the sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination.

The standard EN ISO 11607-2: 2017 is titled 'Packaging for terminally sterilized devices – Part 2 Validation requirements for forming, sealing and assembly processes'.

- 3.2 Packaging for medical equipment which has been cleaned, disinfected and serviced ready for return to use without sterilization is not included in this guidance.

### General principles

- 3.3 When handled in accordance with instructions packaging should protect products from physical damage and maintain the sterility of the product up to the point of use. The method of sealing should ensure that the microbial barrier properties are preserved and, where required, that the pack can be opened aseptically.
- 3.4 The purposes for which packaging is used are:

- to contain the product;
- to permit sterilization of the packaged product;
- to protect the product from deterioration and damage;
- to maintain the sterility of the product through distribution and storage to the point of use;
- to allow aseptic opening at the point of use;
- to prevent contamination of the product.

- 3.5 The packaging should not inhibit the efficacy of the process by, for example, hindering the removal of air or the penetration of sterilant, impeding the conduction of heat to the load, outgassing, altering the humidity in the chamber, or absorbing chemical sterilants.
- 3.6 Only packaging systems that are compatible with the processes used and validated to provide the required microbial barrier properties should be used. It may be necessary to carry out performance qualification tests on the product and its packaging in order to determine the levels and rates of change of temperature, pressure and other cycle variables which start to cause unacceptable changes in the performance qualities of the product or its packaging. This also applies when changing the packaging system.
- 3.7 Sterilization grade wrapping materials and sterile barrier systems complying with the relevant parts of EN ISO 11607 and EN 868 should be used.

**Note:** Compliance to a relevant part of EN 868 does not automatically mean compliance to EN ISO 11607-1: 2017 or EN ISO 11607-2: 2017.

A statement of confirmation of compliance to a relevant part of EN 868 from a manufacturer shall contain a statement whether EN ISO 11607-1 (and EN ISO 11607-2 if relevant) is covered.

Each CDU should evaluate the performance of each sterile barrier system or packaging system before selection and implementation to ensure conditions for sterilization, storage, and handling can be met.

Each CDU that manages sterile medical devices should have a documented plan of education on how to store, handle and transport sterile medical devices. See 'Theatres and CDU Guidance: Management of reusable surgical instruments during transportation, storage and after clinical use' – GUID 5010: 2014 Part B for further operational guidance.

Sterilization grade packaging material chosen for sterile barrier systems (and protective packaging which is applied pre-sterilization) is commonly one of the following types: Single use paper bags, single use plastic/paper reels/pouches, single use sheet wrapping material or re-usable sterilization containers.

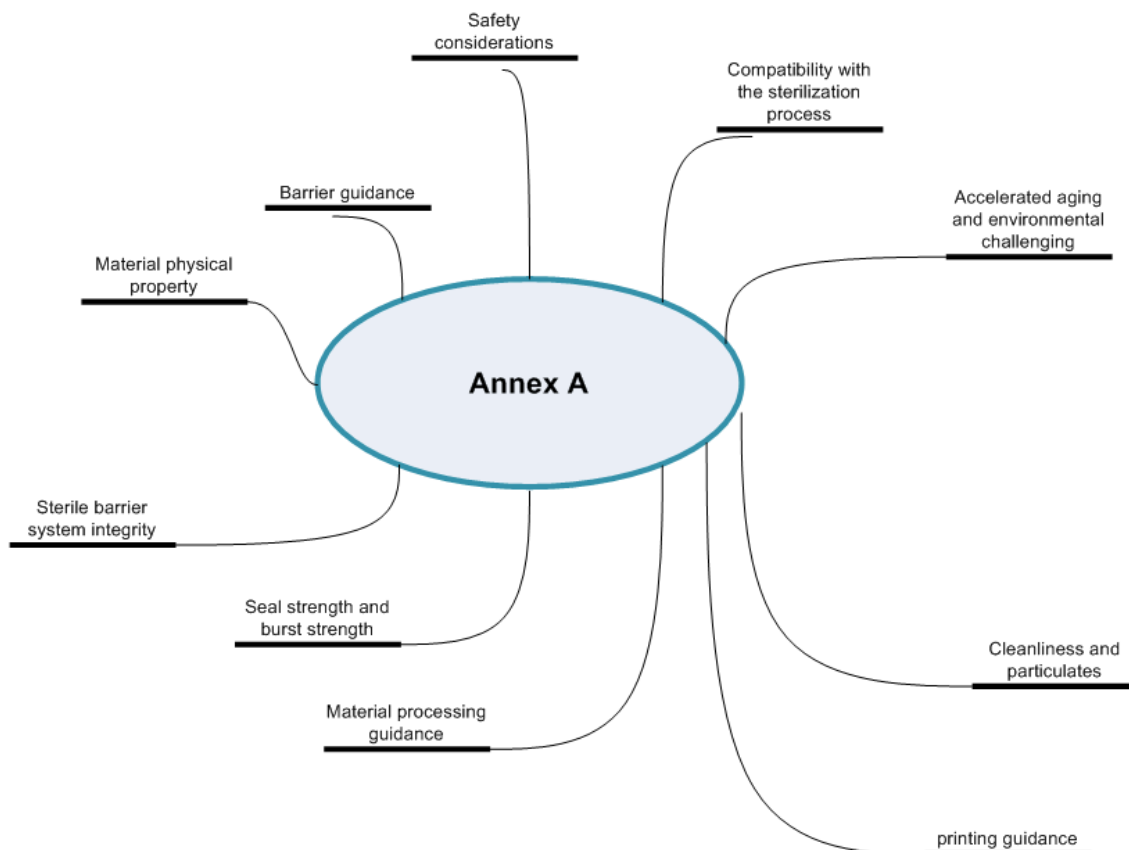
- 3.8 The packaging must:

- permit identification of the number and type of product contained, the lot number, the manufacturer and the expiry date (by labelling);
- the labelling should remain intact and legible throughout handling, transportation and storage;
- include specification of storage conditions which the packaging is designed to withstand;
- provide any necessary instructions for the correct use of the product (by labelling and/or instruction sheets);
- present the product in a manner which allows it to be removed aseptically immediately before use.

### Technical specification CEN ISO/TS 16775

Technical specification (Section 3) of CEN ISO/TS 16775: 2014 covers guidance for health care facilities on conformance to EN 11607-1 and EN 11607-2.

An outline of the design criteria guidance covered in Annex A of CEN ISO/TS 16775 follows, see [Figure 2](#).



**Figure 2: CEN ISO/TS 16775: 2014 Annex A – Design criteria - selection, evaluation and testing of packaging materials and sterile barrier systems**

See [Figure 3](#) for an outline of the various methods of interest concerning sterilization specified in Annex B of CEN ISO/TS 16775: 2014.

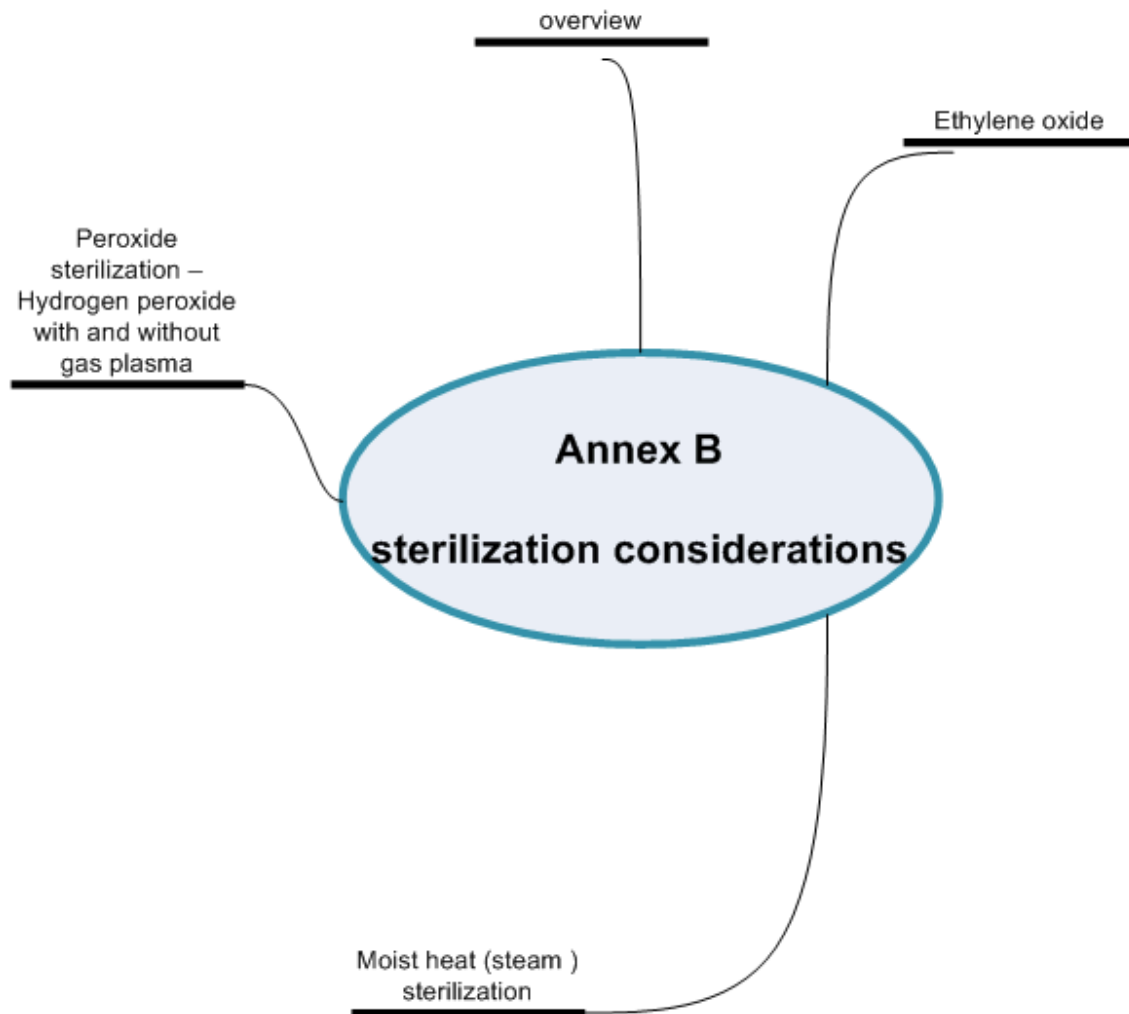


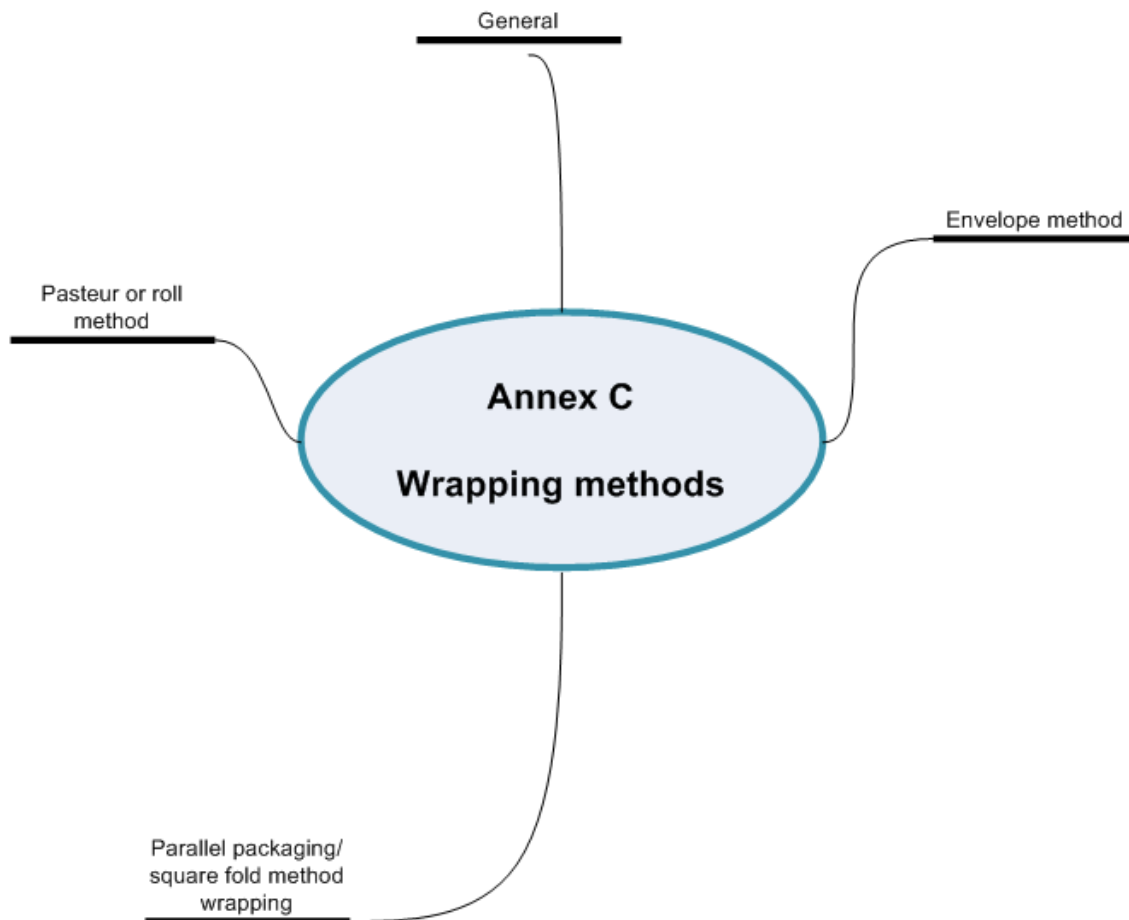
Figure 3: CEN ISO/TS 16775: 2014 Annex B sterilization considerations

## Packaging operations

3.9 The procedures and controls implemented for packaging operations must be designed to ensure that:

- each product produced is in the correct type of pack;
- each pack is correctly and effectively sealed (see [section 3.173](#));
- each pack is correctly labelled with all the necessary information (see [section 3.196](#) 'Requirements for the label on the packaging').

See [Figure 4](#) which describes the various wrapping methods specified in CEN ISO/TS 16775: 2014.



**Figure 4: CEN ISO/TS 16775: 2014 Annex C wrapping methods**

It has been noted that staff have experienced difficulties with aseptic presentation when products are packed using the roll method. There is a need to verify that the SBS in use enables aseptic presentation.

### European standards

- 3.10 A number of harmonised standards are published which are relevant to packaging and labelling of terminally sterilized products.
- 3.11 *EN 1041: 2013 Information supplied by the manufacturer with medical devices.*
- This standard specifies the information to be supplied by the manufacturer of medical devices necessary to comply with the requirements of the Directive.
- 3.12 *EN ISO 15223-1: 2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.*
- This standard defines a number of symbols to be used in labelling medical devices. The use of these symbols will both facilitate provision of all the essential information on small packs.
- 3.13 *EN ISO 11607-1: 2017, Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems.*



Part 1 of EN ISO 11607: 2017 specifies the basic attributes required of materials and pre-formed systems intended for use in packaging systems for terminally sterilized medical devices. In doing so it considers the wide range of potential materials, medical devices, packaging system designs and sterilization methods likely to be encountered by a CDU. It also suggests the tests required for a manufacturer of a packaging system to prove compliance with the standard.

- 3.14 EN ISO 11607 Part 1 replaces EN 868-1 and specifies general requirements for all packaging materials whereas EN 868 Parts 2 to 10 specify particular requirements for a range of commonly used packaging materials and types. Compliance with EN 868 Parts 2 to 10 can be used to demonstrate compliance with one or more of the requirements of Part 1 of EN ISO 11607: 2017.
- 3.15 The term “sterile barrier system” was introduced and is used throughout the document to describe the minimum packaging required to perform the unique functions required of medical packaging:
- to allow sterilization;
  - to provide an acceptable microbial barrier;
  - to allow for aseptic presentation.
- 3.16 “Protective packaging” protects the sterile barrier system, and together they form the packaging system.
- 3.17 An overview of sterile barrier systems can be found in Annex A of EN ISO 11607-1: 2017.
- 3.18 *EN 11607-2: 2017 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.*
- Part 2 of EN ISO 11607 describes the validation requirements for forming, sealing and assembly processes. One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance.
- 3.19 The validation of packaging processes is crucial to ensure that sterile barrier system integrity is attained and maintained until opened by the user of the sterile medical devices.
- 3.20 In order to comply with Part 2 of EN 11607, there should be a documented validation programme demonstrating the efficacy and reproducibility of all sterilization and packaging processes.
- 3.21 The packaging operations that can affect sterile barrier system integrity are forming, sealing, capping or other closure systems, cutting and process handling.

### **EN 868 Series - Packaging for terminally sterilized medical devices.**

- 3.22 This standard EN 868 is presented in a series of separate parts. The original Part 1 has been superseded by EN ISO 11607 but the subsequent parts of the standard specify requirements for a variety of different types of packaging materials and systems. Conformity with the specified requirements in these parts of the standard

may be used as one means of demonstrating compliance with some, or all, of the requirements of EN ISO 11607 Part 1: 2017.

3.23 The individual parts in EN 868 are:

- **Part 2:** Sterilization wrap - Requirements and test methods;
- **Part 3:** Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods;
- **Part 4:** Paper bags - Requirements and test methods;
- **Part 5:** Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods;
- **Part 6:** Paper for low temperature sterilization processes - Requirements and test methods;
- **Part 7:** Adhesive coated paper for low temperature sterilization processes - Requirements and test methods;
- **Part 8:** Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods;
- **Part 9:** Uncoated nonwoven materials of polyolefines - Requirements and test methods;
- **Part 10:** Adhesive coated nonwoven materials of polyolefines - Requirements and test methods.

3.24 As of 2018 all of the parts of EN 868 have either been updated or are in the process of review. Parts 2, 3, 4, 6 and 7 were revised in 2017. Most of the changes were done in order to align with the EN ISO 11607 series, in particular by:

- adopting the terms and definitions used in the EN ISO 11607 series whilst removing additional elements, i.e. deleting “sterile field” and “surgical drape” which are covered by the EN 13795 series;
- incorporating the requirements of EN ISO 11607-1 as general requirements for the EN 868 series standards;
- formulating the significance and limits of the requirements of the EN 868 series standards with respect to the requirements given by EN ISO 11607-1;
- linking the test methods with regard to information on statement of precision and bias, repeatability and reproducibility to EN ISO 11607-1. As a result of this, some of the test methods listed in the annexes of the various parts have been updated or revised;
- providing of informative data for repeatability and reproducibility of the test methods that previously did not include such data.

3.25 CEN ISO/TS 16775: 2014 'Packaging for terminally sterilized medical devices. Guidance on the application of ISO 11607-1: 2014 and ISO 11607-2: 2014'.

The document provides guidance on the application of EN ISO 11607-1 and EN ISO 11607-2. It does not add to, or otherwise change, the requirements and is an

informative document, not normative. Therefore it does not include requirements to be used as basis of regulatory inspection or certification assessment activities.

- 3.26 CEN ISO/TS 16775 should be used to better understand the requirements of ISO 11607-1 and/or ISO 11607-2 and it illustrates some of the variety of methods and approaches available for meeting their requirements. Guidelines are given for evaluation, selection and use of packaging materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Guidance on validation requirements for forming, sealing and assembly processes is also given. It provides useful information for health care facilities and in particular CDUs.

### **Materials used in packaging**

- 3.27 The materials of which the packaging is made will necessarily limit the sterilization processes with which it is compatible as well as affecting its ability to meet other performance requirements. The acceptability of a sterile barrier system and packaging method is dependent upon the medical devices to be wrapped, their use and conditions of storage. Clause 3.2.2.6 of CEN ISO/TS 16775: 2014 provides guidance on selection of appropriate sterile barrier systems to be employed when wrapping medical devices.

### **Textiles used in packaging**

- 3.28 Textiles used require to be in compliance with EN 11607-1. Reusable fabrics have requirements including:
- Performance requirements to be met after any repairs to the material and after every sterilization cycle;
  - Processing procedures for laundering and refurbishing require to be established and documented.
- 3.29 Specialist fabrics are available which are intended to be water repellent while at the same time being gas permeable. This may be achieved by several means, for example a particularly tight weave of polyester fibres. Care needs to be exercised in using these fabrics that the flow rate of both air and steam through the fabric is adequate for the sterilization process. They also require careful inspection for holes and damage. It is for this reason that their use is discouraged as a sterile barrier system although they may be useful as protective packaging. CEN ISO/TS 16775: 2014 D3 Validation plan checklist: wrapping process includes textiles as a sterilization wrap.
- 3.30 Textiles are often used as a wrapping material for heavy packs, especially of orthopaedic theatre medical device.
- 3.31 Textiles are stronger than paper, and stronger than many non-wovens, and will resist tearing and rupture. However, textiles are generally a less efficient bacterial barrier than sterilization grade wrapping paper or non-wovens and should always be used in two or more layers.
- 3.32 Overall textiles are used in limited ways. It should be noted that the test pack loads for sterilizers employ textiles.

- 3.33 The textile wraps should be laundered before each re-use. Control should be exercised over the laundry process to ensure that fabric softeners and fresheners are not used since many of these contain volatile components which will evolve gas during steam sterilization and compromise the efficacy of the sterilization process.
- 3.34 The importance of thorough inspection before re-use cannot be overemphasised. A light table should be used, and wraps with pinholes, clearly visible as points of light, should not be used.
- 3.35 The location of the defect should be clearly marked and the item sent for repair by means of a heat-seal patch. Sewn patches are not acceptable because of the needle holes created around the patch.

### **Papers and non-wovens used in packaging**

- 3.36 Both papers, which are made from cellulose fibres, and non-wovens, made from a combination of cellulosic and synthetic fibres, may be used. Both types are suitable for porous-load steam sterilization and most low temperature processes because they are permeable to air, steam and other gases.
- 3.37 These are available as plain sheets, creped sheets which give better drape characteristics, as bags and in combination with a plastic film as pouches (or reel material from which pouches can be made).
- 3.38 Good drape and handle characteristics are also provided by crepe paper (EN 868-2).
- 3.39 Plain papers may be used as wraps or preformed into bags or pouches. The bags and pouches may be plain sided or may be gusseted to accommodate bulky medical devices.
- 3.40 Wet strength and water repellency are specifically improved over “normal” papers by the impregnation of the paper with high wet-strength resins.
- 3.41 The water content of the paper may be maintained at a relatively high level, thus improving the feel and drape of the paper and minimising superheating due to exothermal rehydration, by the addition of humectants such as sorbitol.
- 3.42 Over many years experience the various forms of paper packaging have been demonstrated to provide an effective microbial barrier.
- 3.43 The EN 868 series of European Standards exist for all the paper packaging materials and should be used as the basis for purchasing specifications.
- 3.44 Non-woven materials, made from a combination of natural and synthetic fibres are also widely used. These are often used where previously re-usable textiles would have been used. They have higher tear and puncture resistance and are softer with better drape qualities. They may also show extremely good water repellence.

### **Synthetic materials and laminates used in packaging**

- 3.45 Polymeric materials, or plastics, may be used in the manufacture of rigid, semi-rigid, or flexible packaging systems. They may be in the form of sheet or film, which is non-porous, or be produced as a spun-bonded or non-woven sheet which is porous.

- 3.46 Film or sheet material may be an absolute barrier to microbes if it is free from pinholes. Although it may be non-porous that does not necessarily mean that it will be impermeable. Most polymers have some permeability to gas, air, and water vapour. The extent of the permeability varies with temperature, concentration gradient of the diffusing substance etc.
- 3.47 Polyethylene is effectively impermeable to air and water and is not suitable therefore for general use in ethylene oxide sterilization processes without special precautions. However very thin films (up to 0.076 mm) thick allow the passage of ethylene oxide (by dissolving in the thin film and then evaporating from the inner surface). Paper laminated with a thin polythene film may thus be used to provide a heat sealable paper for use in ethylene oxide sterilization.
- 3.48 High-density polyethylene is produced as a spun-bonded, non-woven (known commercially as Tyvek) paper-like material. It is very tough, and although it is porous like paper it is water repellent. In commercial use it has been found to provide a satisfactory bacterial barrier. It is frequently used in packs which are to be ethylene oxide or hydrogen peroxide sterilized and may be used with a clear film in the form of a pouch, as venting panels in impermeable bags made of, for example polythene, or as a sealing lid on blister packs.
- 3.49 It has also been found suitable for use in steam sterilizers operating at sterilization temperatures up to 121°C.
- 3.50 It has some disadvantages in that it may attract dust and fibres owing to its electrostatic character, it can be difficult to print on and also it may be difficult to seal, although these latter difficulties largely can be overcome by using non-oil based inks and lacquering with a suitable heat-seal lacquer, respectively. It is also expensive compared with paper.
- 3.51 At temperatures above 125°C even high-density polythene has softened too much to be used on its own as an effective packaging material. Therefore it is likely to be only suitable for a 121°C cycle.
- 3.52 Polyester, in the form known as oriented or crystallised polyester, is used as a laminate with polythene in the construction of paper/plastic pouches and reel material. The polythene forms the inner surface which is heat sealed to the paper. The outer layer of the plastic laminate is polyester which gives the required mechanical strength at elevated temperature as well as a good printing surface.
- 3.53 Polyvinyl chloride (PVC) generally has a very low stability to both heat and ionising radiation. PVC will absorb ethylene oxide in large amounts. This is exacerbated by the ethylene oxide combining with the phthalate plasticiser, from which it is aerated only very slowly under ambient conditions. Therefore it should not be used as a packaging material for ethylene oxide sterilization.
- 3.54 Nylon is heat stable, and is also steam permeable but it is impermeable to air. Packaging constructed entirely from nylon film is unsuitable for steam sterilization because the air retained in the package may interfere with effective sterilization. It may however be used effectively in combination with a porous material, such as paper, to form a steam-sterilizable pouch.

### **Metals used in packaging**

- 3.55 Metals are used in the fabrication of sterilization containers for use in both steam and to a lesser extent in gas processes such as ethylene oxide. Since the material is neither porous nor permeable it must be constructed with a suitable venting system for use in hospital sterilization processes.
- 3.56 The choice of metal should be based on consideration of both its corrosion resistance to the sterilization process, for example in a steam atmosphere, and on its thermal characteristics. The ideal material would have a high thermal conductivity and a low heat capacity and would attain the required temperature quickly, uniformly and without the formation of excessive amounts of condensate.
- 3.57 In practice, the choice is usually between aluminium, anodised or otherwise surface treated to give it suitable corrosion resistance, and a suitable grade of stainless steel.

### **Purchase, quality control and storage of packaging materials**

- 3.58 Packaging materials should be purchased, handled and controlled in compliance with the CDU's quality management system operated to standard EN 13485: 2016. These should be validated, with accessories, prior to purchase, to ensure their effectiveness and avoid adverse events due to for example, staining, residue, damage etc. Refer to Part A of SHTM 01-01 and consult NP for procurement of consumables.

#### **Purchase of packaging materials**

- 3.59 All packaging materials should be purchased, whenever possible, to an international or European standard or other suitable specification from approved suppliers. Packaging materials that are used as a sterile barrier system must be purchased to the relevant EN ISO 11607 and EN 868 series standards.
- 3.60 Packaging material should be purchased only to an agreed, written specification. When it is intended to purchase a catalogue item, the specification for that item should be obtained from the supplier and used as the basis of that purchase, and all subsequent purchases of the material. This should ensure that the user is informed of any changes in specification subsequently made by the supplier.
- 3.61 The purchase order should be based on the quantity which can reasonably, be expected to be used within the manufacturer's stated shelf life.
- 3.62 Although paper products and other packaging materials, have a prolonged shelf life the manufacturer's expiry date may relate to other properties such as a process indicator or a heat-seal adhesive whose performance may deteriorate on storage.
- 3.63 The packaging materials should be supplied suitably wrapped to provide the required protection when it is stored under the specified conditions. A pre-purchase trial may be beneficial.

#### **Quality control of packaging materials**

- 3.64 In many cases users of packaging materials will lack the facilities necessary to carry out a comprehensive independent assessment of delivered materials for conformity to their purchase specification. Nevertheless every reasonable step should be taken to establish conformity. This requires that each delivery should be examined to ensure that:

- there is no visible damage to the shipment;
- the delivery note, the label description and the purchase order are in agreement concerning the quality, size and number of the material;
- that each consignment has clearly identifiable lot numbers;
- that each lot delivered is accompanied by a Certificate of Analysis or Certificate of Conformity, or if the delivery is a further supply from a lot previously received that the appropriate certificate is on record.

- 3.65 When, due to the nature of the packaging, it is necessary to carry out tests, other than a visual inspection, on incoming packaging materials a random sample should be taken and submitted for analysis.
- 3.66 There should be a formal sampling plan which should take account of:
- the quantity received;
  - the quality required;
  - the nature of the material, and the risk involved if the material is not to specification;
  - the established reliability of the packaging manufacturer.
- 3.67 In confirming that the material supplied is identical in every respect with the material ordered particular attention should be paid to printed labels and packaging materials.
- 3.68 A system for segregating delivery of packaging materials which have not been examined from those which have been found suitable for use should be implemented.
- 3.69 Packaging materials should be stored under conditions which are maintained within those specified by the manufacturer of the packaging. This is best achieved by environmental control of the storage area.
- 3.70 The temperature, and where necessary the humidity, of the storage environment should be monitored with a maximum-minimum thermometer and hygrometer, even if the store is not environmentally controlled.
- 3.71 Paper and other moisture sensitive packaging materials should not be stored adjacent to:
- external walls or other surfaces which may be at a lower temperature than the ambient temperature of the store;
  - sources of heat which could cause dehydration of the packaging material.
- 3.72 Sheet materials should be stored flat, not on edge.
- 3.73 Packaging materials should be stored on shelves, clear of the floor.
- 3.74 Pre-printed labels and other printed packaging materials should be stored in secure conditions which exclude unauthorised access and should be transported in separate containers in order to avoid mix-ups.

- 3.75 Packaging materials should be issued for use only by authorised personnel following an approved and documented procedure.
- 3.76 Outdated or obsolete packaging material, especially printed material, should be destroyed and this disposal recorded.

## **Methods of packing**

### **Use of paper, non-woven, synthetic or textile sheets in packing**

- 3.77 Wrapping may be performed sequentially or simultaneously. Different methods can be used for the different layers. Care should be taken to limit the area covered by tape and labels to ensure adequate porous area for effective sterilization and drying.
- 3.78 Annex C of PD CEN ISO/TS 16775: 2014 provides guidance (including diagrams) on appropriate wrapping methods to be employed when wrapping medical devices using sheets of sterilization wrap.

### **Use of paper bags, paper/plastic pouches in packing**

- 3.79 Folding is the simplest method to obtain a satisfactory closure for both pouches and bags, although it may not be convenient for high volume production.
- 3.80 The corners at the open end of the bag or pouch are folded diagonally to give mitred corners. The top of the bag or pouch is then folded over three times in succession and secured in place with a piece of high-temperature masking tape, or autoclave indicator tape. The folds should be approximately 12mm in size.
- 3.81 The folded top should always be secured with tape; staples should never be used because of the holes that are then made in the package.
- 3.82 The folded top may be opened by cutting through the bag or pouch with a pair of sterile scissors. For non-critical applications it may be torn open; it should not be opened by removing the tape and unfolding the closure.
- 3.83 Self-seal bags and pouches are closed by folding as described for plain top bags and pouches, above. However the bag or pouch is manufactured with an impact adhesive coating in a small area of the paper, which is protected before use by a piece of “release paper”.
- 3.84 When the bag has been filled the top is folded over as previously described, the release paper is removed and the adhesive patch is pressed onto the surface of the bag to secure the folded top in place.

### **Heat sealing**

- 3.85 Paper bags and paper/plastic pouches and reel material are available in forms suitable for heat sealing.
- 3.86 The melting point of the heat-seal will effectively limit the maximum temperature at which the pack can be used. Heat-seal packaging should not be used at temperatures above those specified by the packaging manufacturer.



- 3.87 Heat sealing is performed by compressing the opposing sides of packaging, coated on one or both inner surfaces with a lacquer, adhesive or polymer film, between heated plates.
- 3.88 Packaging intended for heat sealing may be film coated, grid lacquered or have an adhesive band.
- 3.89 Film-coated heat-seal packaging has a thin film of a suitable polymer, such as polythene, laminated to the inner surface. When heated this melts sufficiently to fuse with the opposing surface and form a seal. The heat-seal polymer may be laminated to another plastic or to paper. The polymer film, if applied to the paper element, may limit the porosity of the pack.
- 3.90 Grid-lacquered heat-seal packaging has one side, usually the paper, printed with a heat-seal adhesive in a repeating diamond pattern all over the inner surface. Care needs to be taken that the width of the heat-seal is sufficient to ensure that there is a continuous seal across the width of the packaging.
- 3.91 Adhesive-coated heat-seal packaging has a band of heat-seal adhesive printed on the inner surface of the packaging in the area where the heat-seal is to be made. The adhesive is coloured, usually blue, to aid identification of the heat-seal area.
- 3.92 The seals need to be peelable. They should peel without splitting, tearing or shedding paper fibres since fibres can cause adverse reactions if introduced into open wounds. Peelability is a compromise between seal strength and the peel characteristics required which can only be achieved by use of the correct heat-sealing conditions.
- 3.93 The heat-seal may be a single line, in which case it should be not less than 5 mm deep and extend across the width of the pack, or a series of lines each about 1 mm wide and 1 mm apart to give a seal width of about 9 mm, with each line extending across the full width of the pack.
- 3.94 The heat-sealing process must be undertaken with care. Creases in the packaging material can result in inadequate or uneven seals. A weak point in the heat-seal of paper bags may often be found in the corners where the paper is folded back on itself and in gusseted packs where four thicknesses of material become two. This latter problem can be minimised by reverse folding the gusset in the area to be heat sealed, before sealing.
- 3.95 The effect of the sterilization process on heat seals must be considered. The elevated temperatures involved in steam sterilization can weaken the seals. Ethylene oxide gas leaves many seals unaffected but can cause embrittlement of others.
- 3.96 Heat sealing is not only used for flexible packaging. It may be used also on rigid packaging when lids are sealed onto moulded plastic bases. The base tray may be moulded in-line just before filling or may be pre-formed. The lid may be of paper or other porous material for use in steam or gas sterilization processes.

**Note:** Good Practice Tips when selecting heat sealed peel packaging. These are taken from DIN 58953-7 Sterilization - Sterile Supply - Part 7: Use Of Sterilization Paper, Nonwoven Wrapping Material, Textile Materials, Paper Bags And Sealable Pouches And Reels

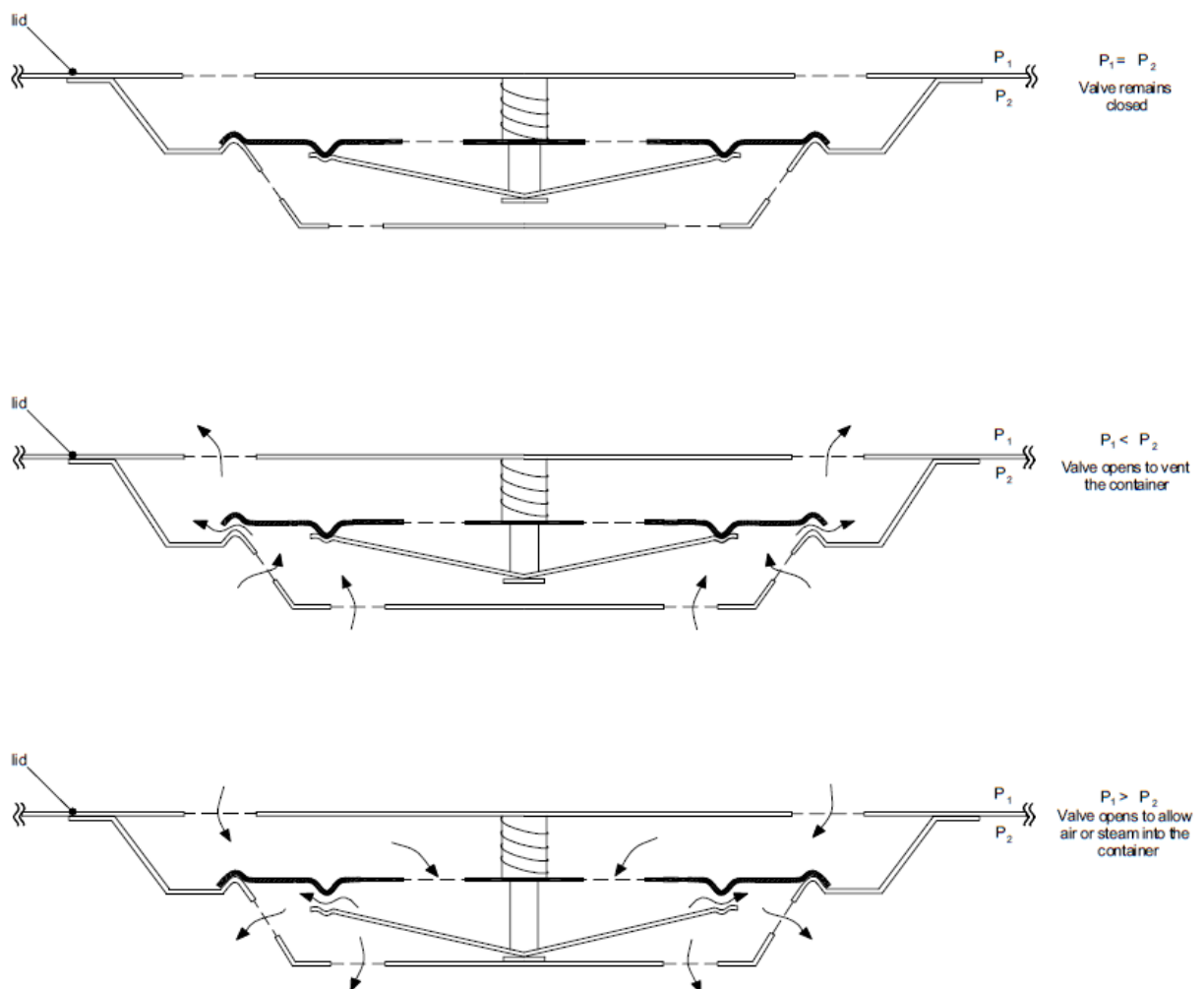
1. Select preformed pouches in accordance with the size of the medical device;
2. If no preformed pouches are available in the correct size, cut reels to an appropriate size and seal at the lower edges such that the reel section can be filled like a pouch. Alternatively, a preformed pouch can also be shortened. Neither the sterile barrier system nor the protective packaging should be kinked or folded;
3. The medical device may occupy at most 75 % of the pouch (DIN 58953-7);
4. The width chosen must allow for unimpeded introduction of the medical device, but it is not advisable to use a bigger size;
5. The space between the upper end of the medical device and the seal seam on the peeling side must be at least 3 cm (DIN 58953-7);
6. After sealing, an excess of at least 1 cm must be left above the seal seam (recommended in practice: 2–3 cm) to allow for unimpeded peeling as well as aseptic withdrawal (DIN 58953-7);
7. When using gusseted pouches or reels the distance to the seal seam should be more than 3 cm to permit orderly sealing of original folds (the folded foil lies evenly on the paper side to prevent formation of any additional folds).

### **Design/construction of sterilization trays, containers and their associated filters**

- 3.97 Trays for containing sets of theatre medical device, or similar, are often constructed in aluminium. Plastics such as polypropylene may also be used. The trays may have solid bases and sides, be of a mesh construction or be equipped with drainage ports/holes to allow condensate formed during steam sterilization to run off.
- 3.98 When condensate drainage is provided it is necessary to ensure that the condensate is not discharged onto other parts of the sterilizer load, which will then emerge from the sterilizer wet.
- 3.99 Trays may be overwrapped in textiles, single-use wraps or bags, or a combination of these materials to achieve the required protection, absorbency and microbial barrier properties in line with validation standard EN 11607-2: 2017.
- 3.100 Instrument orientation trays, usually constructed in metal, are fitted with retaining clips designed to hold a particular set of medical device in position. They are often found in dental practice and also for use with sets of orthopaedic medical device and rigid endoscopic medical device. They are almost invariably fully vented or mesh construction.

- 3.101 Re-usable rigid containers are intended for use as a packaging system in steam (and in some cases, gas) sterilization processes. These are intended to contain medical devices which will be used in a single clinical procedure.
- 3.102 EN 868-8: 2009 specifies performance requirements for rigid re-usable containers.
- 3.103 Container systems are constructed in a variety of materials and those from various manufacturers differ greatly in design, construction and mode of operation. The containers are constructed from impermeable materials. The joint between the lid and the base is sealed by means of a suitable gasket, which should be accessible for inspection and cleaning between uses.
- 3.104 In order to permit the flow of gases (air and steam and, where applicable, sterilant gas) in and out of the container that is required by the sterilization process the containers are fitted with one or more sterilant ports, see [Figure 5](#).
- 3.105 Two different operating principles are used for the sterilant ports, although both may be used in combination. The exchange of gases may be through a porous filter material or through a valve system.
- 3.106 The filter system is little different in principle from the porous packaging systems considered previously. Its compatibility with the sterilization process depends on its porosity and on being able to provide the necessary flow rate through the filter to permit attainment of the sterilizing conditions within the container. The ability to maintain sterility depends on the filter efficacy and whether it is able to exclude particles of a size which may contain viable organisms. The small area of surface available compared with the volume of the pack produces relatively high flow rates across the filter material and this influences the materials which can be used effectively.
- 3.107 If a re-usable filter is used then great care is needed to ensure that:
- it has not become partially blocked, thus impairing the flow of gases and compromising the sterilization process;
  - it has not been damaged, thus allowing the passage of unfiltered gases which would compromise the maintenance of sterility.
- 3.108 Both re-usable and single-use filters need to be installed correctly and checked so that the filter is effectively sealed in the holder and there is no passage of unfiltered gases around the filter.
- 3.109 The alternative system for sterilant ports is the valve system. Outside the sterilizer the valve is normally closed and, if the seals on the valves are effective, presents an impermeable barrier to external contamination. The valve system has to be arranged to open automatically in the sterilizer to permit the exchange of gases between the container and the environment.
- 3.110 A number of systems are used by the various manufacturers but most depend on valves which open in response to a pressure difference between the container and its surroundings. A diagram of the operation of such a system is shown, see [Figure 5](#).

- 3.111 It is apparent that a finite pressure difference must exist across the valve before it will open. The magnitude of the pressure difference will depend on the force exerted by the springs keeping the valve closed.
- 3.112 If the pressure difference required to open the valve is too great, the contents of the container will not be exposed to the sterilizing conditions in the sterilizer chamber. The correct functioning of the container is closely related to the pressure change characteristics of the sterilization cycle. If the required pressure difference is too small the valve will open outside the sterilizer due to changes in ambient pressure and temperature, thus allowing the inflow of unfiltered air from the environment.



**Figure 5: Diagram to show the principle of operation of value-type reusable container systems**

- 3.113 Some container systems are also fitted with a valve in the base of the container which is used to allow condensate to drain away, to assist in drying the contents of the container.

- 3.114 The condensate drain valve may be fitted with a thermostatic device to open the valve when it is above a specified temperature, say 80°C, or it may operate on pressure differential as previously described for valved sterilant ports.
- 3.115 After repeated use, the springs controlling a valved system will age and the force exerted by them will change. It is essential that the manufacturer's instructions for maintenance, testing and replacement of key components such as seals, sterilant ports and drainage valves are followed rigorously.
- 3.116 The performance of either type of container may be seriously affected both by the nature of the sterilization cycle (particularly the characteristics of the air removal phase and the drying stage) and by variations in the quality of services supplied to the sterilizer (for example the dryness fraction of the steam). These variables are sterilizer and site specific respectively.
- 3.117 It is necessary, therefore, to establish, by appropriate on-site testing, that any particular design which it is intended to use functions correctly in the specific sterilization cycle with which it is to be processed, in the sterilizers which will be used in practice.
- 3.118 Re-usable containers have a number of apparent advantages. They offer excellent mechanical protection to the contents and a convenient, modular system for storage and distribution.
- 3.119 The use of a solid-walled container gives the impression of providing good protection against microbial and other environmental contamination. In practice the barrier properties are dependent on the adequacy of gaskets and seals and the sterilant ports described above.
- 3.120 The condition and function of filters, valves, sealing gaskets and locking systems needs to be verified on each container before each use. Between uses containers should be disassembled and cleaned following the manufacturer's recommendations. These should be performed in a washer/disinfector.
- 3.121 The choice of detergent should accord strictly with the manufacturers' recommendations since a number of cleaning agents in common use can cause corrosion or surface cracking on the metal or plastic surface of containers.
- 3.122 Most containers are fitted with interior baskets or mesh trays used to hold the instruments. These may be suitable to contain returned medical device as they are processed through a washer disinfector.
- 3.123 In use the containers need to be properly loaded if they are to be used successfully. The manufacturers' recommendations concerning the maximum weight, the proportion or density of rubber or metal ware and the presence and location of absorptive materials in the load should be followed.
- 3.124 Some containers are intended to be used in conjunction with porous packaging materials, either as an inner or outer layer of packaging, whereas others are intended to be used, and will only function correctly, without any other packaging being present during sterilization. It is important that the manufacturer's instructions for use are followed.

- 3.125 Containers which are not intended for use with a second layer of packaging, that is those which can only function as a single packaging layer, are not suitable for use in an aseptic environment.
- 3.126 Containers manufactured to the EN 868 Part 8: 2009 will be sized in relation to the standard loading module for large steam sterilizers (see EN 285: 2015). High packing densities within the sterilizer chamber can be achieved and it is important to ensure that the maximum permitted load for the sterilizer is not exceeded.
- 3.127 To avoid problems with moisture retention within the container it may be necessary to increase the time allowed for the drying stage of the sterilization cycle.
- 3.128 Each container should be fitted with a tamper evident closure system which should provide a clear indication when the integrity of the closure has been compromised.
- 3.129 The containers are designed to stack for storage purposes. Containers from any one manufacturer should stack securely but containers of different provenance may not. When purchasing this type of packaging system all the containers should be from the same manufacturer to ensure compatibility.
- 3.130 Re-usable containers are often promoted on the basis that they are more cost effective than single-use packaging. A decision based on cost grounds requires careful evaluation of the initial capital cost, cleaning and maintenance costs (including all equipment, components, consumables and labour required), the working life (the number of re-uses) which the manufacturer is prepared to guarantee, the likelihood of damage or loss and the cost of eventual disposal.

### **Specific requirements for ethylene oxide process packaging**

- 3.131 Packaging materials and methods should be selected which are compatible with the ethylene oxide sterilization process and which maintain sterility and the quality of the packaging system. Packaging should be designed to allow removal of air and penetration of both steam and ethylene oxide. Impervious packaging materials are unsuitable for ethylene oxide sterilization.
- 3.132 There are a considerable number of different ethylene oxide sterilization processes ranging from those employing pure ethylene oxide at sub atmospheric pressures to those which use a mixture of ethylene oxide and carbon dioxide at pressures of several bar. Therefore, packaging suitable for one ethylene oxide sterilizer may not be suitable for another. For example, package seals may be weakened and possibly fail in a cycle with relatively high humidity and several large and rapid changes in pressure, where seals of the same type would have been satisfactory for a cycle employing less extreme conditions.
- 3.133 The extent to which packaging absorbs or adsorbs ethylene oxide and its permeability to ethylene oxide may have a major influence on the efficacy of the cycle and the subsequent aeration process. Cartons (shelf packs, transit cartons) may be convenient but they may increase the humidification time, the gas exposure time and subsequent level of ethylene oxide residuals.
- 3.134 Because of the need to control humidity, the extent to which packaging absorbs moisture may have a major influence on the efficacy of the process and must be considered before a satisfactory humidification stage can be demonstrated.

- 3.135 Process control is also a concern since packaging material that has become dehydrated may absorb excessive moisture during the conditioning phase; if this possibility were not recognised during validation the achieved cycle lethality may be adversely affected.
- 3.136 The standard on validation of ethylene oxide sterilization processes (EN ISO 11135-1: 2014. 'Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices') includes the requirement that the packaging specification be part of the definition and documentation of the sterilization process. The validation report should include or reference details of product sterilized, including packaging specification and load patterns in the sterilizer.
- 3.137 It is therefore necessary that during the physical and microbiological performance qualification studies the medical devices should be packaged in an identical manner to that to be used routinely when they are presented for sterilization.
- 3.138 The introduction of a new, or altered, packaging material or system requires validation. Physical and microbiological performance qualification studies should be performed on the introduction of new or modified packaging, although demonstration of equivalence to a previously validated package would satisfy this requirement. Refer to the NP contract for consumables.
- 3.139 In practice, many of the packaging materials routinely used for steam sterilization in hospitals are equally suitable for ethylene oxide because of similar permeability requirements. However, Users should be aware that because of the lower temperatures employed in the ethylene oxide process a wider range of materials is available.
- 3.140 In particular, the sterile barrier system, and inks should be able to withstand elevated humidity and temperatures (typically  $\leq 60$  °C, high humidity), deep repeated vacuums, nitrogen and ethylene oxide. Temperature and humidity ranges will vary with the design of the sterilization cycle.
- 3.141 The sterile barrier system needs to have porous areas that allow gas to pass in and out. Gas transport through the permeable portion needs to occur at a rate sufficient to maintain sterile barrier system integrity during the vacuum and/or fill process.
- 3.142 Care should be taken to ensure that the configuration of individual sterile barrier systems contained in a sterile barrier system and/or packaging system does not impede their permeability. Close contact of the permeable material with a non-permeable one should be avoided as this may prevent the gas from penetrating.
- 3.143 Paper bags or plastic/paper pouches are usually found to be most convenient for small articles. Wrapping in sheets of high-density polyethylene, plain or crepe paper, or textiles, may be required for large procedure trays containing endoscopes or other thermolabile equipment.
- 3.144 Moulded foam inserts may also be used to provide protection for sensitive equipment such as endoscopes.
- 3.145 Polythene bags with gas exchange ports are also suitable.

## Specific requirements for hydrogen peroxide process packaging

- 3.146 Packaging materials and methods should be selected which are compatible with the hydrogen peroxide sterilization process and which maintain sterility and the quality of the packaging system. Packaging should be designed to allow removal of air and penetration of vaporised hydrogen peroxide.
- 3.147 There are a considerable number of different vaporised hydrogen peroxide sterilization processes in the market. The methods of sterilant delivery and removal of residual hydrogen peroxide vary tremendously across different manufacturers. This fact and the absence of a published specific international standard for these types of process mean that, although unlikely, it is possible that packaging suitable for one sterilizer may not be suitable for another. Therefore the manufacturer of the particular sterilizer should be consulted regarding the use of suitable sterile barrier systems and protective packaging.
- 3.148 Some hydrogen peroxide sterilizers have a gas plasma generation stage for breakdown of residual hydrogen peroxide (See Part E of SHTM01-01 for further information). If plasma is used, the sterile barrier system and/or packaging system, and ink should be compatible with the plasma, and with the plasma generation process.
- 3.149 In practice, whilst some of the packaging materials used for steam sterilization in hospitals are suitable for hydrogen peroxide because of similar permeability requirements many are not. Cellulose products (including paper) cannot be used or processed in hydrogen peroxide sterilizers.
- 3.150 The sterile barrier system and/or packaging system, and ink to withstand temperature up to 55 °C with Relative Humidity (RH) up to 80 % for the duration of the validated cycle. The sterile barrier system and/or packaging system, and ink should not be sensitive to deep vacuum or hydrogen peroxide.
- 3.151 The sterile barrier system and/or packaging system need to have porous areas that allow gas to pass into and out of the sterile barrier system and/or packaging system. Gas transport through the permeable portion needs to occur at a rate sufficient to maintain sterile barrier system integrity during the vacuum and/or fill process.
- 3.152 High-density polyethylene pouches are usually found to be most convenient for small articles. Wrapping in sheets of high-density polyethylene may be required for large procedure trays containing endoscopes or other thermolabile equipment.

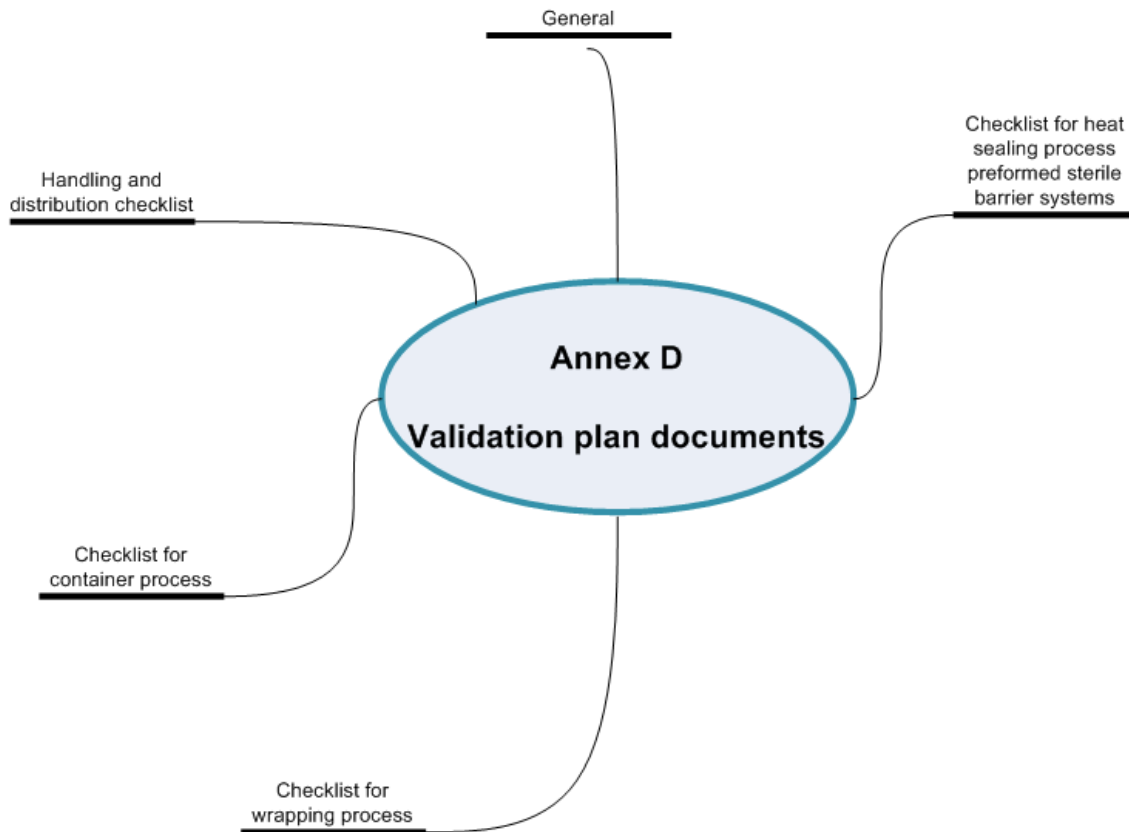
## Validation of packaging systems

### Introduction

- 3.153 Before a particular packaging system is adopted for a medical device, or a group of similar medical devices, it should be evaluated to establish validation requirements. This evaluation should be documented. See [Figure 6](#) which outlines documents to consider that are detailed in Annex D of the technical specification CEN ISO/TS 16775: 2014. Part 2 of EN ISO 11607: 2017 describes the validation requirements for forming, sealing and assembly processes. One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. The validation of packaging processes is crucial



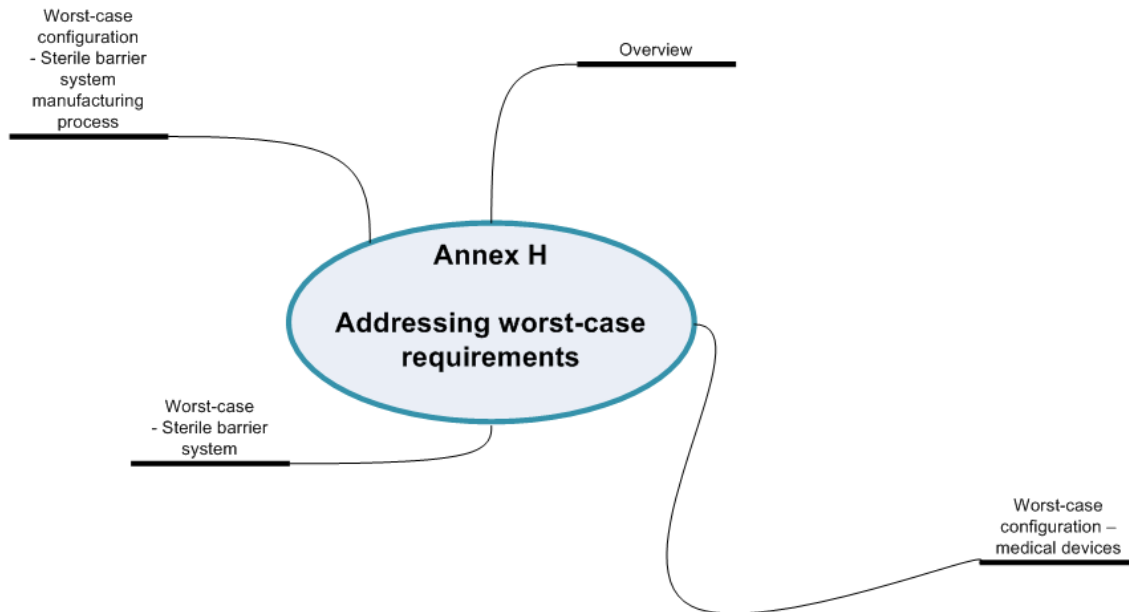
to ensure that sterile barrier system integrity is attained and maintained until opened by the user of the sterile medical devices. In order to comply with Part 2 of EN 11607, there should be a documented validation programme demonstrating the efficacy and reproducibility of all sterilization and packaging processes. The packaging operations that can affect sterile barrier system integrity are forming, sealing, capping or other closure systems, cutting and process handling.



**Figure 6: Documents to consider as part of the validation planning as Annex D of CEN ISO/TS 16775: 2014**

- 3.154 Specific testing may not be necessary when appropriate data are available, historically from similar use from the manufacturers of the packaging system or from an independent third party.
- 3.155 The compatibility of the packaging with the sterilization process can be established for many packaging systems by demonstrating conformity of the packaging and the sterilization process with published standards. For example when using sterilization-grade paper bags manufactured in conformity to EN 868-4: 2017 in accordance with the packaging manufacturers recommendations, for use in a sterilizer conforming to EN 285: 2015 and operated in accordance with the guidance given in this SHTM compatibility may be presumed.
- 3.156 However if the process involves using those same standardised packaging products in a configuration or combination with other standardised products not likely to have been tested previously (e.g. multiple combinations of sheets from different manufacturers) then validation may be required.
- 3.157 The compatibility of the packaging with the labelling system will usually be established by using the labelled pack for such tests as may be necessary.

- 3.158 The compatibility of the packaging with the service user's requirements at the point of use, for example aseptic opening, should be verified by consultation with them. Testing is rarely required. See [Figure 7](#) which details the contents of Annex H of CEN ISO/TS 16775: 2014 on addressing worst-case requirements.

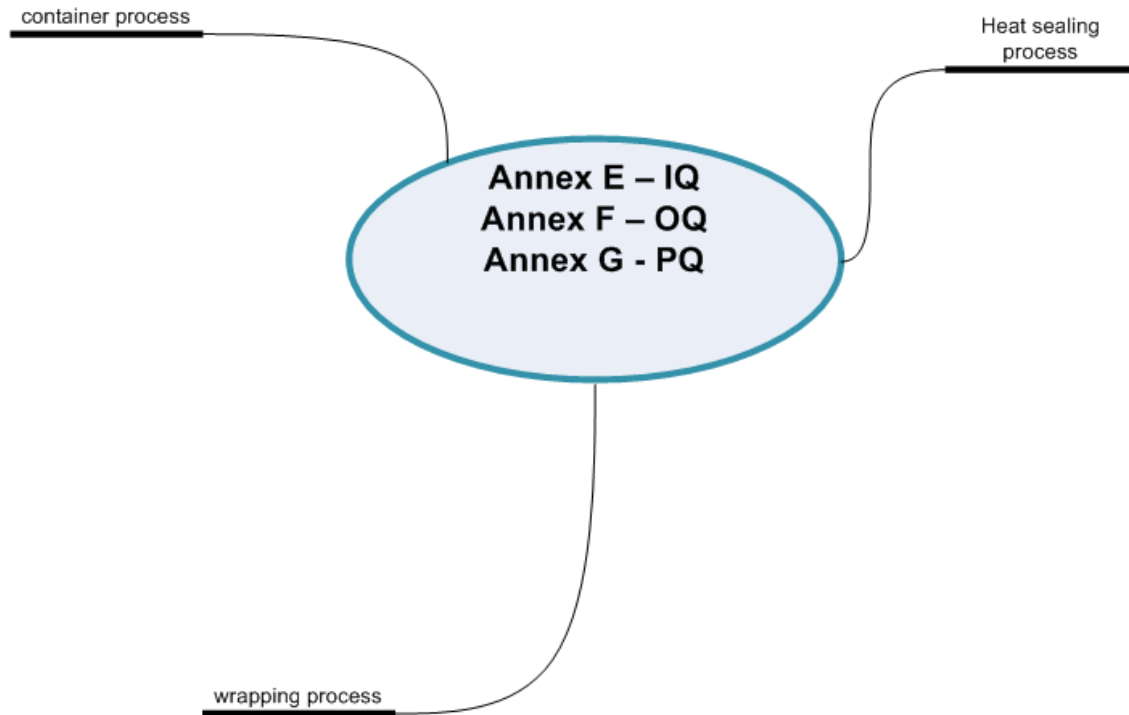


**Figure 7: Addressing worst-case requirements as Annex H of CEN ISO/TS 16775: 2014**

- 3.159 The sensitivity of the pack contents to particular risks, such as irradiation, moisture, mechanical shock, static discharge and the compatibility of the packaging with the contents, for example the medical device, in other words, that the packaging has no adverse effect on the medical device or vice versa, will usually be apparent from historical data. When new medical devices are to be packaged and sterilized, the instructions for use which the medical device manufacturer is required to provide should be followed.
- 3.160 By using packaging systems that comply with the relevant EN ISO 11607 and EN 868 series standards, the protection provided by the packaging against adverse environmental influences will have been evaluated by the manufacturer. These standards include minimum requirements for tear resistance, bursting strength (both wet and dry), air permeance, water repellence, pore diameters and tensile strength (both wet and dry).
- 3.161 If not using such packaging systems, adequate performance of the packaging should be demonstrated under the anticipated conditions of use by simulating the abuses a pack may encounter during routine methods of transit and storage.
- 3.162 By using packaging systems that comply with EN ISO 11607, the protection provided by the packaging against microbial contamination will have been evaluated by the manufacturer.
- 3.163 If not using such packaging systems the protection provided by the packaging against microbial contamination should also be evaluated and meet validation standards.

**Note:** The packaging should also protect against environmental conditions and handling. The evaluation should also consider the ability of the sterilant to penetrate through the packaging system, any residue condensate on products and other accessories such as sponges placed in corners to reduce sharp edges. These sponges may release unwanted ink or chemicals.

- 3.164 Tests for bacterial penetration of packaging may be carried out by specialist subcontractors.
- 3.165 The microbial barrier properties of a sterile pack are dependent on both the materials of which the packaging is made and the construction of the package.
- 3.166 Package testing may be avoided by the compilation of evidence that the materials of construction are themselves an adequate barrier together with evidence that all seals and closures are adequate barriers.
- 3.167 Demonstrating that the barrier material is impermeable can satisfy the microbial barrier requirement. The impermeability of a material shall be determined in accordance with Annex C of EN ISO 11607-1: 2017.
- 3.168 Evaluation of the microbial barrier properties of porous materials is typically conducted by challenging samples with an aerosol of bacterial spores or particulates. Data from a validated physical test method that correlates with a validated microbiological challenge method are considered acceptable for determining the microbial barrier properties. Table B.1 of Annex B of EN ISO 11607-1: 2017 contains a list of test methods that can be considered.
- 3.169 For packaging materials to be used in gas sterilization processes it may be necessary to determine the extent and nature of microbial contamination on the packaging before sterilization. This should not be necessary for steam sterilization processes operating at 134°C for not less than three minutes.
- 3.170 When knowledge of the packaging bioburden is required this information should be sought from the packaging manufacturer or it should be determined in accordance with EN ISO 11737-1: 2018 'Sterilization of medical devices - Microbiological methods. Determination of a population of microorganisms on products.'
- 3.171 When re-usable packaging systems are being evaluated it is important that the cleaning, inspection and maintenance procedures and methods are also evaluated for their ability to consistently restore the packaging system to the required condition for re-use.
- 3.172 Annexes E, F and G of CEN ISO/TS 16775: 2014 provide detailed proformas and guidance for validation of sterile barrier systems. See [Figure 8](#) which shows the Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) for various packing processes. Additional information can also be found in the Guideline for the validation of packaging processes according to ISO 11607-2, published by the German Society of Sterile Supply Deutsche Gesellschaft für Sterilgutversorgung, DGSV e. V.) 2012.



**Figure 8: Qualifications exercises for various packaging processes as Annexes E, F & G in CEN ISO/TS 16775: 2014**

### Validation of seals and closures

- 3.173 The methods available for verification of the adequacy of the seal or closure depend on the method chosen. Seals formed in impermeable packaging materials can be tested by one of several leak test methods but these are not generally applicable to seals formed in porous materials, nor to closures which rely upon a tortuous path to exclude microbial contamination.
- 3.174 Closures which rely on a tortuous path formed by folding are very dependent for their success on the skill of the operator forming the closure. There is good published evidence, from a number of studies carried out over many years, that the closures described in Annex C of PD CEN ISO/TS 16775: 2014 are satisfactory.
- 3.175 Heat seals are dependent for their success on the performance of the heat sealer used.

**Note:** Several patterns of heat sealer are in common use. Hand-operated heat sealers with scissor action jaws designed for sealing light gauge polythene bags are rarely satisfactory for sterilization packaging. Parallel-jaw sealers, which may be hand or foot operated, have one of the jaws heated and this presses against the opposing unheated jaw. Heat-seal packaging placed between the jaws is heated and compressed. Heat-seal conveyors work in a similar manner.

The seal integrity and strength is affected by the temperature, pressure and dwell time of the heat-sealing equipment. The design of many heat sealers makes effective monitoring, calibration and adjustment of the operating conditions difficult.

Any heat sealer which is to be used for sealing packs for sterilization should be monitored regularly for the controlling variable of temperature, pressure and dwell time. Machines which cannot be independently tested should not be used.

### Validation & operation of heat sealers

- 3.176 The heat sealer should be validated at installation (using an IQ, OQ and PQ process) and be subject to routine periodic validation in line with the heat sealer manufacturer's instructions for use.
- 3.177 Clause 3.3.2.7 of technical specification CEN ISO/TS 16775: 2014 provides guidance on validation of heat sealers.
- 3.178 The quarterly and yearly periodic tests to be performed on a heat sealer are specified, see [Table 1](#). A proforma and calculation for reporting of thermometric results is also shown, see [Table 2](#). Three batches or sets of sealed sterile barrier systems should be made; these batches should encompass the potential significant sources of variation such as operator, time of day, material (size, source, and lot), sterile barrier system contents. Package contents that present the greatest challenge (worst-case) should be included.

Test		Frequency (Quarterly = Q, Yearly = Y)	
Recording of key critical variables including temperature, temperature uniformity, pressure, pressure uniformity, dwell time.		Q	Y
Verification of calibration (using the procedure and tolerances recommended by the manufacturer of the sealing machine).		Q	Y
Thermometric measurement of actual seal temperature (using thermometric measuring equipment specified in Part B of this SHTM)			Y
Visual test of seal integrity	Intact seal for a specified seal width	Q	Y
	No channels or open seals, no bubbles.	Q	Y
Visual test of package integrity - No punctures or tears		Q	Y
Seal strength (tested according to Annex D of *EN 868-5:2009. EN 868-5 indicates a minimum reference value of 1.5 N per 15 mm for steam sterilization processes and 1.2 N per 15 mm for other sterilization processes)			Y
Peelability (tested according to Annex E of EN 868-5:2009)			Y

**Table 1: Heat sealer quarterly and yearly periodic tests**

\*EN 868-5:2009 was being revised in 2018.

Verification of calibration (in °C)	Measured temperature	Indicated temperature
Seal Temperature	Lower limit	Upper limit
Temperatures recommended by the preformed sterile barrier system manufacturer (LL and UL)		
Actual temperature achieved during the test (AL and AU)		
Temperatures achieved during the test were within the limits recommended by the preformed sterile barrier system manufacturer ( $T \geq LL$ and $T \leq UL$ )	<input type="checkbox"/> yes <input type="checkbox"/> no	
Temperature (T) (mean value from AL and AU values of actual temperature at the time of testing)	T =	
Switch-off tolerance in degrees (according to sealing device manufacturer's specifications, max. $\pm 5$ °C)	Aberration (A) A =	
Results lower and upper value	T - A =	T + A =
Conditions	T - A $\geq$ LL	T + A $\leq$ UL
Compliant with conditions?	<input type="checkbox"/> yes <input type="checkbox"/> no	<input type="checkbox"/> yes <input type="checkbox"/> no

**Table 2: Heat sealer annual thermometric periodic tests proforma**

### Operation of heat-sealing equipment

- 3.179 Sealing machines must be in good condition, properly set and maintained to the manufacturer's specification, and closing and sealing operations should be under constant supervision.
- 3.180 For heat-sealing operations the critical variables of temperature, temperature uniformity, pressure, pressure uniformity, dwell time, and the characteristics of the packaging materials, for example the type, thickness and uniformity of the heat-seal adhesive, should, ideally, be verified at regular intervals.
- 3.181 The efficacy of the seals should be tested and proved on a regular basis, not less than daily for each heat sealer when in use.
- 3.182 As a minimum daily heat-sealing records should be kept and these should be reviewed quarterly; there should also be a quarterly check on the temperature control of each heat sealer.
- 3.183 Several methods for testing heat seals are available. For daily production checks, a dye penetration test or a test using a commercially available seal indicator paper can be performed.
- ### Dye penetration test (ink test)
- 3.184 EN ISO 11607-1: 2017 designates the dye penetration test as a test method for verification of the integrity of seal seams.
- 3.185 Materials and prerequisites:

- sealing device must be switched on and ready for operation (target temperature reached);
- dye penetration test pack\*:
  - suitable test ink with defined, very low viscosity;
  - pipette;
  - liquid-impermeable underlay;
  - if necessary, small disposable cloth, handkerchief, or similar.
- reel sections or pouches (approx. 20 cm width) of all see through packaging needed for the dye penetration test.

*\*Complete test packs are commercially available.*

### 3.186 Method:

- switch sealing device to test mode (if applicable);
- seal an empty pouch or reel section; width at least 20 cm/length approx. 10 cm;
- cut the pouch approximately 5 cm above the sealing seam (the reel section is already open at the top);
- using a pipette, inject around 2 ml of dye penetrant into the opened pouch or reel section just above the sealing seam. Using a finger or cloth, rub the testing ink along the sealing seam from the outside;
- after around 20 seconds, check whether the sealing seam is intact.

### 3.187 Pass Criteria:

- seal leaks in the sealing seam will be visible from the penetration of test ink out of the pouch. The test is a pass if no ink passes the seal.

**Note:** If left for a long time the extremely thin-liquid test ink can penetrate the porous material (paper or Tyvek) of the pouch or reel. This is not a leak.

### Particular requirements for validation of re-useable containers

- 3.188 Re-usable containers should be subjected to thermometric performance tests before they are adopted as a packaging system. This may be accomplished using a container modified to provide a gas-tight thermocouple entry port and carrying out tests essentially similar to the small load and full load thermometric tests described in SHTM 01-01 Part C and EN 285: 2015. Instead of the thermocouples being inserted on a Bowie and Dick test pack, they should be inserted into the lumens of devices, the outside of devices and to the walls of the container. At least 7 thermocouples (including 1 in the chamber reference measurement point) should be used. A modified container is shown, see [Figure 9](#).



**Figure 9: Modified re-useable container with gas-tight thermocouple entry port for thermometric tests**

- 3.189 The tests should be carried out with a container fully loaded with medical devices of the type which it is intended to process. If both medical device and textiles are to be processed, the container should be tested under both fully loaded conditions. The full load test should be carried out with the sterilizer fully loaded with fully loaded containers.
- 3.190 The temperature profile obtained should not show any significant delay in the contents of the container equilibrating with the sterilization temperature in the chamber, when compared to the results obtained using a small-load test pack.
- 3.191 Throughout the holding time the temperature measured at the reference measurement point of the sterilizer chamber, any temperature measured within the test pack and the theoretical temperature of the saturated steam determined from the measured sterilizer chamber pressure shall:
- a) be within the sterilization temperature band;
  - b) not differ from another by more than 2 K (2°C).
- 3.192 Load dryness should be verified using a modified metal load test based upon that described in EN 285: 2015 clause 20.3. The test shall be modified by using the containers fully loaded with medical devices of the type which it is intended to process in place of the metal test pack.
- 3.193 The result should comply with clause 8.3.3 of EN 285: 2015 e.g. the calculated change in moisture value shall not exceed 0.2 %.
- 3.194 Clause 3.3.2.9 of CEN ISO/TS 16775: 2014 provides further guidance on validation of re-useable container systems.
- 3.195 The sealing surfaces of the base and lid should be inspected for damage at each time of use to ensure the proper closure of the container. There should be no visible damage, contamination or material irregularities. Follow the manufacturer's instructions for use for checking at each use and maintenance requirements



**Note:** Consultation draft prEN 868-8: titled Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods, was released in 2017.

The draft proposed test methods and values for re-usable containers used as sterile barrier systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use. The containers are intended to be used in steam sterilizers conforming to EN 285. The need for a packaging material inside the container is determined by the manufacturers and users. Other than the general requirements as specified in EN ISO 11607-1 and EN ISO 11607-2 this part of EN 868 specifies materials, test methods and values that are specific to the products covered by this European Standard. The draft indicated that when additional materials are used inside the sterile barrier system in order to ease the organization, drying or aseptic presentation (e.g. inner wrap, indicators, packing lists, mats, instrument organizer sets, tray liners or an additional envelope around the medical device) then other requirements, including the determination of the acceptability of these materials during validation activities, can apply.

The following are considered in the draft:

Shape and dimension, Lids and lid-latching devices, Tamper evident closure system, Gasket, Carrying devices, Stacking capability, Sterilant Port, Load and Service life.

Annexes consider:

Guidance on dimensions, Carrying device strength test, Stacking test – Procedure, Stacking device capability test, Determination of sterilization performance, Load, dryness tests and Guidance on determination of useful life with respect to sterilization.

## Requirements for the label on the packaging

- 3.196 The particulars on the label shall be indelible, easily legible and clearly comprehensible to the intended user or patient. For reusable containers the label from the previous sterilization cycle should be removed prior to attaching the new label. Any residue adhesive from a label should be removed from the reusable containers.
- 3.197 Information on the packaging which maintains the sterile condition of a device ('sterile packaging') The following particulars shall appear on the sterile packaging: (a) an indication permitting the sterile packaging to be recognised as such, (b) a declaration that the device is in a sterile condition, (c) the method of sterilisation, (d) the name and address of the manufacturer, (e) a description of the device, (f) if the device is intended for clinical investigations, the words 'exclusively for clinical investigations', (g) if the device is custom-made, the words 'custom-made device', (h) the month and year of manufacture, (i) an unambiguous indication of the time limit for using or implanting the device safely expressed at least in terms of year and month, and (j) an instruction to check the instructions for use for what to do if the sterile packaging is damaged or unintentionally opened before use. Sourced from the EU medical device regulation EU 2017/745 Annex I 'General Safety and Performance Requirements', Chapter 3 'Requirements Regarding the Information Supplied with the Device'.

## Process indicators

- 3.198 A system to differentiate between processed and unprocessed packaged medical devices should be used.
- 3.199 Single-use packaging materials may be obtained pre-printed process indicators suitable for one or more sterilization processes. For other packaging materials suitable process indicators may be purchased printed onto adhesive packaging tape, adhesive patches or onto labels.
- 3.200 Whichever system is chosen the process indicator should conform to the requirements of the relevant part of the EN ISO 11140 'Sterilization of health care products — Chemical indicators series'. Ensure the process indicator is compatible with the packaging system.
- 3.201 For reusable containers, the previously exposed process indicator (from previous cycle) should be removed prior to attaching a new unexposed indicator.

## References

These references were current at the time this document was produced. Anyone using this document should ensure that they refer to the current versions of any references.

### Standards

**EN 285: 2015- Sterilization.** Steam sterilizers. Large sterilizers. CEN.

**EN 868-2: 2017 - Packaging for terminally sterilized medical devices. Sterilization wrap.** Requirements and test methods. CEN.

**EN 868-3: 2017 - Packaging for terminally sterilized medical devices - Part 3:** Paper for use in the manufacture of paper bags (specified in EN 868-4) and in the manufacture of pouches and reels (specified in EN 868-5) - Requirements and test methods. CEN.

**EN 868-4: 2017 - Packaging for terminally sterilized medical devices - Part 4:** Paper bags - Requirements and test methods. CEN.

**EN 868-5: 2009 - Packaging for terminally sterilized medical devices - Part 5:** Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods. CEN.

**EN 868-6: 2017 - Packaging for terminally sterilized medical devices - Part 6:** Paper for low temperature sterilization processes - Requirements and test methods. CEN.

**EN 868-7: 2017 - Packaging for terminally sterilized medical devices - Part 7:** Adhesive coated paper for low temperature sterilization processes - Requirements and test methods. CEN.

**EN 868-8: 2009 - Packaging for terminally sterilized medical devices - Part 8:** Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods. CEN.

**EN 868-9: 2009 - Packaging for terminally sterilized medical devices - Part 9:** Uncoated nonwoven materials of polyolefines - Requirements and test methods. CEN.

**EN 868-10: 2009 - Packaging for terminally sterilized medical devices - Part 10:** Adhesive coated nonwoven materials of polyolefines - Requirements and test methods. CEN.

**EN 1041: 2008+A1: 2013 - Information supplied by the manufacturer of medical devices.** CEN.

**EN ISO 11607-1: 2017 - Packaging for terminally sterilized medical devices. Part 1** Requirements for materials, sterile barrier systems and packaging systems. CEN.

**EN 11607-2: 2017 - Packaging for terminally sterilized medical devices - Part 2:** Validation requirements for forming, sealing and assembly processes. CEN.

**EN ISO 11135: 2014 - Sterilization of health-care products.** Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices. CEN.

**EN ISO 11140-1: 2014 - Sterilization of health care products.** Chemical indicators. General requirements. CEN.

**EN ISO 11737-1: 2018 - Sterilization of medical devices.** Microbiological methods. Determination of a population of microorganisms on products. CEN.

**EN ISO 13485: 2016 - Medical devices.** Quality management systems. Requirements for regulatory purposes. CEN.

**EN ISO 14644-2: 2015 Cleanrooms and associated controlled environments.** Specifications for testing and monitoring to prove continued compliance with ISO 14644-1. CEN.

**EN ISO 14698-1,2: 2003 Cleanrooms and associated controlled environments.** Biocontamination control. General principles and methods. CEN.

**EN ISO 15223-1: 2016 - Medical devices.** Symbols to be used with medical device labels, labelling and information to be supplied. General requirements. CEN.

**EN ISO 17664: 2017 – ‘Processing of health care products. Information to be provided by the medical device manufacturer for the processing of medical devices’.** CEN.

### Technical specification

**CEN ISO/TS 16775: 2014 - Packaging for terminally sterilized medical devices.** Guidance on the application of ISO 11607-1 and ISO 11607-2. CEN.

### Consultation draft standards 2017/2018

**Draft prEN 868-8: 2017** Packaging for terminally sterilized medical devices. Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 - Requirements and test methods. CEN.

**Draft prEN 868-5: 2017** Packaging for terminally sterilized medical devices – Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods. CEN.

**prEN 17141: September 2018** Cleanrooms and associated controlled environments -- Biocontamination control. CEN.

### HFS publications

**Scottish Health Technical Memorandum (SHTM) 01-01 Decontamination of medical devices in a Central Decontamination Unit - Part A: Management, 2018.**

**Scottish Health Technical Memorandum (SHTM) 01-01 Decontamination of medical devices in a Central Decontamination Unit - Part B** Test Equipment/methods, 2018.

**Scottish Health Technical Memorandum (SHTM) 01-01 Decontamination of medical devices in a Central Decontamination Unit - Part C:** Sterilization by steam, 2018

**Scottish Health Technical Memorandum (SHTM) 01-01 Decontamination of medical devices in a Central Decontamination Unit - Part D:** Automated cleaning and disinfection equipment, 2018.

**Scottish Health Technical Memorandum (SHTM) 01-01 Decontamination of medical devices in a Central Decontamination Unit - Part E** Sterilization by hydrogen peroxide or ethylene oxide, 2018.

**Theatres and CDU Guidance:** Management of reusable surgical instruments during transportation, storage and after clinical use – GUID 5010: 2014 Parts A & B.

**Scottish Health Planning Note 13 Part 1:**2010 Decontamination Facilities: Central Decontamination Unit. HFS, 2010.

#### **Other Guidance**

**DIN 58953-7: 2010 - Sterilization - Sterile Supply - Part 7:** Use Of Sterilization Paper, Nonwoven Wrapping Material, Textile Materials, Paper Bags and Sealable Pouches and Reels.

**Red Book, Reprocessing of Instruments to Retain Value:** 10th anniversary edition 2016, published by the Instrument Reprocessing Working Group.

**Guideline for the validation of packaging processes according to ISO 11607-2:** published by the German Society of Sterile Supply (Deutsche Gesellschaft für Sterilgutversorgung, DGSV e. V.) 2012.