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15	**临床评价报告**	方案报告
16	**上市后产品监督计划（PMCF）**	
17	**上市后产品报告**	上市后产品报告
18	**易用性（可用性）报告**	IEC_62366-可用性报告
19	**风险管理报告（CE）**	符合ISO 14971要求的风险分析报告
20	**风险管理报告（国内）**	
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25	**降解方案及报告**	编写降解方案（符合国内、ce、FDA要求），检测报告

INTERNATIONAL STANDARD

ISO 11607-1

Second edition
2019-02

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage

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Contents

Page

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11607-1:2006), which has been technically revised. It also incorporates the amendment ISO 11607-1:2006/Amd.1:2014.

The main changes compared to the previous edition are as follows:

— the definitions have been aligned with the latest version of ISO 11139;

— new requirements for the evaluation of usability for aseptic presentation have been added;

— new requirements for the inspection of sterile barrier system integrity prior to use have been added;

— a new subclause with requirements for revalidation in accordance with ISO 11607-2 has been added;

— Annex B has been updated and various national, international and European test methods have been added or deleted;

— a new Annex D has been added with environmental considerations;

— a new Annex E has been added with draft guidance on ways to differentiate a sterile barrier system from protective packaging.

A list of all parts in the ISO 11607 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The process of designing and developing a packaging system for terminally sterilized medical devices is a complicated and critical endeavour. The device components and the packaging system should be combined to create a sterile medical device that performs efficiently, safely and effectively in the hands of the user.

This document specifies requirements for the design of sterile barrier systems and packaging systems for terminally sterilized medical devices, the basic attributes required of materials and preformed sterile barrier systems, and design validation requirements. This document is written as a general (horizontal) standard considering a wide range of potential materials, medical devices, packaging system designs and sterilization methods. It can be applied by suppliers of materials or of preformed sterile barrier systems, by medical device manufacturers or health care facilities. ISO 11607-2 describes the process development and validation requirements for forming, sealing and assembly processes and addresses controls during normal operations.

Guidance for ISO 11607 series can be found in ISO/TS 16775.

European standards that provide requirements for particular materials and preformed sterile barrier systems are available and known as the EN 868 series. Conformity with the EN 868 series can be used to demonstrate conformity with one or more of the requirements of this document.

The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility up to the point of use and allow aseptic presentation. The specific nature of the medical device, the intended sterilization methods(s), the intended use, expiry date, transport and storage all influence the packaging system design and choice of materials.

The term “sterile barrier system” was introduced in ISO 11607-1:2006 to describe the minimum packaging required to perform the unique functions required of medical packaging: to allow sterilization, to provide an acceptable microbial barrier, and to allow for aseptic presentation. “Protective packaging” protects the sterile barrier system, and together they form the packaging system. “Preformed sterile barrier systems” would include any partially assembled sterile barrier systems such as pouches, header bags or hospital packaging reels. An overview of sterile barrier systems is given in Annex A.

The sterile barrier system is essential to ensure the safety of terminally sterilized medical devices. Regulatory authorities recognize the critical nature of sterile barrier systems by considering them as an accessory or a component of a medical device. Preformed sterile barrier systems sold to health care facilities for use in internal sterilization are considered medical devices in many parts of the world.

Packaging for terminally sterilized medical devices —

Part 1: Requirements for materials, sterile barrier systems and packaging systems

1 Scope

This document specifies requirements and test methods for materials, preformed sterile barrier systems, sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices until the point of use.

It is applicable to industry, to health care facilities, and to wherever medical devices are placed in sterile barrier systems and sterilized.

It does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements can be necessary for drug/device combinations.

It does not describe a quality assurance system for control of all stages of manufacture.

It does not apply to packaging materials and/or systems used to contain a contaminated medical device during transportation of the item to the site of reprocessing or disposal.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5636-5, *Paper and board — Determination of air permeance (medium range) — Part 5: Gurley method*

ISO 11607-2, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
aseptic presentation
transfer of sterile contents from its sterile barrier system using conditions and procedures that minimize the risk of microbial contamination

[SOURCE: ISO 11139:2018, 3.13]

3.2
bioburden
population of viable microorganisms on or in product and/or sterile barrier system

[SOURCE: ISO 11139:2018, 3.23]

3.3
closure
<packaging> means used to complete a sterile barrier system where no seal is formed

EXAMPLE By a reusable container gasket or sequential folding to construct a tortuous path.

[SOURCE: ISO 11139:2018, 3.51, modified — The example has been added.]

3.4
closure integrity
<packaging> characteristics of a closure to minimize the risk of ingress of microorganisms

[SOURCE: ISO 11139:2018, 3.52]

3.5
control
regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.6
expiry date
date by which product should be used

Note 1 to entry: For the purpose of this document and ISO 11607-2, expiry date refers to the medical device in a sterile barrier system. The term "use by date" (3.29) is used to describe the shelf life of packaging materials and preformed sterile barrier systems prior to assembly into a sterile barrier system.

[SOURCE: ISO 11139:2018, 3.110, modified — Note 1 to entry has been added.]

3.7
labelling
label, instructions for use and any other information that is related to identification, technical description, intended purpose and proper use of the health care product, but excluding shipping documents

[SOURCE: ISO 13485:2016, 3.8, modified — The term "medical device" has been replaced by "health care product".]

3.8
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

— diagnosis, prevention, monitoring, treatment or alleviation of disease;

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury;

— investigation, replacement, modification, or support of the anatomy or of a physiological process;

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

— items specifically intended for cleaning or sterilization of medical devices;

— pouches, reel goods, sterilization wrap and reusable containers for packaging of medical devices for sterilization;

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

— devices for *in vitro* fertilization or assisted reproduction technologies.

[SOURCE: ISO 13485:2016, 3.11, modified — The first two list items in Note 1 to entry have been added.]

3.9
microbial barrier
property of a sterile barrier system to minimize the risk of ingress of microorganisms

[SOURCE: ISO 11139:2018, 3.169]

3.10
monitoring
continual checking, supervising, critically observing, or determining the status, in order to identify change from the performance level required or expected

[SOURCE: ISO Guide 73:2009, 3.8.2.1, modified — The note has been deleted.]

3.11
packaging system
combination of a sterile barrier system and protective packaging

[SOURCE: ISO 11139:2018, 3.192]

3.12
preformed sterile barrier system
sterile barrier system (3.23) that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags and open *reusable containers* (3.17).

[SOURCE: ISO 11139:2018, 3.201, modified — The example has been added.]

3.13
product
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), health care product(s).

Note 1 to entry: For the purpose of this document and ISO 11607-2, products include preformed sterile barrier systems, sterile barrier systems, and contents within them.

[SOURCE: ISO 11139:2018, 3.217, modified — Note 1 to entry has been added.]

3.14
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

[SOURCE: ISO 11139:2018, 3.219]

3.15
repeatability
condition of measurement, out of a set of conditions that includes the same measurement procedure, same operators, same measuring system, same operating conditions and same location, and replicate measurements on the same or similar objects over a short period of time

[SOURCE: ISO/IEC Guide 99:2007, 2.20, modified — The term name has been simplified and the notes omitted.]

3.16
reproducibility
condition of measurement, out of a set of conditions that includes different locations, processors, measuring systems, and replicate measurements on the same or similar objects

Note 1 to entry: The different measuring systems may use different measurement procedures.

Note 2 to entry: A specification should give the conditions changed and unchanged to the extent practical.

[SOURCE: ISO/IEC Guide 99:2007, 2.24, modified — The term name has been simplified.]

3.17
reusable container
rigid *sterile barrier system* (3.23) designed to be used repeatedly

[SOURCE: ISO 11139:2018, 3.235]

3.18
seal
<packaging> result of joining surfaces together by fusion to form a microbial barrier

Note 1 to entry: Surfaces can be joined together by, for example, adhesives or thermal fusion.

[SOURCE: ISO 11139:2018, 3.244, modified — Note 1 to entry has been added.]

3.19
seal integrity
<packaging> characteristics of a seal to minimize the ingress of microorganisms

[SOURCE: ISO 11139:2018, 3.245]

3.20
seal strength
mechanical capacity of the seal to withstand force

[SOURCE: ISO 11139:2018, 3.246]

3.21
service life
number of processing cycles and/or lifetime up to which a product is claimed to remain suitable and safe for its intended use when used according to the labelling

[SOURCE: ISO 11139:2018, 3.251]

3.22
sterile
free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]

3.23
sterile barrier system
SBS
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile contents at the point of use

[SOURCE: ISO 11139:2018, 3.272]

3.24
sterile fluid-path packaging
system of protective port covers and/or packaging designed to ensure sterility of the portion of the medical device intended for contact with fluids

EXAMPLE The interior of the tubing for administration of an intravenous fluid.

[SOURCE: ISO 11139:2018, 3.273]

3.25
sterilization compatibility
<packaging> attributes of the packaging material and/or system that allow it both to withstand the sterilization process and attain the required conditions for sterilization within the packaging system

[SOURCE: ISO 11139:2018, 3.278]

3.26
sterilizing agent
physical or chemical entity, or combination of entities, having sufficient microbiocidal activity to achieve sterility under specified conditions

[SOURCE: ISO 11139:2018, 3.288]

3.27
terminal sterilization
process whereby a product is sterilized within its sterile barrier system

[SOURCE: ISO 11139:2018, 3.295]

3.28
terminally sterilized
condition of a product that has been exposed to a sterilization process in its sterile barrier system

[SOURCE: ISO 11139:2018, 3.296]

3.29
use by date
upper limit of the time interval during which the performance characteristics of a material and/or preformed sterile barrier system, stored under the specified conditions, have been demonstrated

3.30
validation
confirmation process, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The objective evidence needed for a validation is the result of a test or other form of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word “validated” is used to designate the corresponding status.

Note 3 to entry: The use conditions for validation can be real or simulated.

[SOURCE: ISO 9000:2015, 3.8.13, modified — "process" has been added to the definition.]

3.31
verification
confirmation, through the provision of objective evidence, that specified requirements have been fulfilled

Note 1 to entry: The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.

Note 2 to entry: The word "verified" is used to designate the corresponding status.

[SOURCE: ISO 9000:2015, 3.8.12, modified — The original Note 2 to entry has been deleted and Note 3 has been renumbered as Note 2 accordingly.]

4 General requirements

4.1 Quality systems

The activities described within this document shall be carried out within a formal quality system.

NOTE ISO 9001, ISO 13485, and ANSI/AAMI ST90 contain requirements for suitable quality systems. Additional requirements can be specified by a country or region.

4.2 Risk management

The activities described within this document shall consider risk management to medical devices.

NOTE ISO 14971 contains requirements for risk management to medical devices. Additional requirements can be specified by a country or region.

4.3 Sampling

The sampling plans used for testing of materials, sterile barrier systems or packaging systems shall be applicable to materials, sterile barrier systems or packaging systems being evaluated. Sampling plans shall be based upon statistically valid rationale.

NOTE Common statistically based sampling plans as given, for example, in ISO 2859-1 or ISO 186 (with appropriate modifications if necessary) can be applied to materials, sterile barrier systems or packaging systems. Additional sampling plans can be specified by countries or regions. For further guidance, see ISO/TS 16775.

4.4 Test methods

4.4.1 A rationale for the selection of appropriate tests for the packaging system shall be established and recorded.

4.4.2 A rationale for acceptance criteria shall be established and recorded.

NOTE Pass/fail is a type of acceptance criterion.

4.4.3 All test methods used to show conformity to this document shall be validated and documented by the laboratory performing the test.

NOTE Annex B contains a list of test methods. Publication of a method by a standards body does not make it validated in any laboratory.

4.4.4 The test method validation shall demonstrate the suitability of the method as used. The following elements shall be included:

— determination of test method repeatability;

— determination of test method reproducibility;

— establishment of test method sensitivity for integrity tests.

4.5 Documentation

4.5.1 Demonstration of conformity with the requirements of this document shall be recorded.

4.5.2 All records shall be retained for a specified period of time. The retention period shall consider factors such as applicable requirements, expiry date and traceability of the medical device or sterile barrier system.

4.5.3 Records of conformity with the requirements shall include, but is not limited to, performance data, specifications and test results from validated test methods as well as validation protocols, conclusions and any necessary actions.

4.5.4 Electronic records, electronic signatures and handwritten signatures executed to electronic records that contribute to validation, process control or other quality decision-making processes shall remain legible, readily identifiable and retrievable.

5 Materials, preformed sterile barrier systems and sterile barrier systems

5.1 General requirements

5.1.1 Materials and/or preformed sterile barrier systems shall be selected to fulfil the goals of a terminally sterilized medical device packaging system.

NOTE 1 Conformity with one or more requirements of this document can be demonstrated by using one or more parts of the EN 868 series.

NOTE 2 A confirmation of conformity to a part of the EN 868 series is not sufficient to be in full conformity with this document.

NOTE 3 Guidance on sustainability aspects is given in Annex D.

The requirements on materials shall apply to those used in preformed sterile barrier systems, as well as sterile barrier systems.

5.1.2 The requirements listed in 5.1 are not intended to be all-inclusive. Characteristics not listed in this subclause may be evaluated using the usability and performance criteria given in Clauses 7 and 8.

5.1.3 The conditions under which the material and/or preformed sterile barrier system are produced and handled shall be established, controlled and recorded, if applicable, in order to ensure the following:

a) the conditions are compatible with the use for which the material and/or sterile barrier system is designed;

b) the performance characteristics of the material and/or sterile barrier system are maintained;

c) the material and/or sterile barrier meets the specification.

5.1.4 As applicable, the influences of the following shall be evaluated and recorded:

a) temperature range;

b) pressure range;

c) humidity range;

d) maximum rate of change of the above, where necessary;

e) exposure to sunlight or UV light;

f) cleanliness;

g) bioburden;

h) electrostatic properties.

5.1.5 The source, history and traceability of all materials, especially recycled materials, shall be known and controlled to ensure that the preformed sterile barrier system and/or sterile barrier system will consistently meet the requirements of this document.

NOTE With current commercial technologies, it is unlikely that anything other than virgin manufacturing waste will be used in recycled materials, due to insufficient controls to allow the safe use of other recycled material in sterile barrier systems.

5.1.6 The following properties shall be evaluated:

a) microbial barrier (see 5.2);

b) biocompatibility and toxicological attributes;

NOTE This is usually restricted to material in contact with the device. Guidance on biocompatibility is given in ISO 10993-1. For further guidance, see ISO/TS 16775.

c) physical and chemical properties;

d) compatibility with respect to forming, sealing and assembly processes;

e) compatibility with respect to the intended sterilization process(es) (see 5.3);

f) any use by date limitations for pre-sterilization storage and shelf-life limitations for post-sterilization storage.

5.1.7 Materials, e.g. wrapping materials, paper, plastic film, nonwovens or reusable fabrics, shall meet the following general performance requirements.

a) Materials shall be non-leaching and odourless under specified conditions of use, to such an extent that neither performance nor safety is impaired and the medical devices with which they are in contact are not adversely affected.

NOTE Odour determination does not require a standardized test method, since odours are readily evident.

b) Materials shall be free of holes, cracks, tears, creases or localized thickening and/or thinning sufficient to impair functioning.

c) Materials shall have a basis weight (mass per unit area) which is consistent with the specified value.

d) Materials shall exhibit acceptable levels of cleanliness, particulate matter and linting.

e) Materials shall conform to established specific or minimum physical properties, such as tensile strength, thickness variation, tear resistance, air permeance and burst strength.

f) Materials shall conform to established specific chemical characteristics (e.g. pH value, chloride, and sulfate content) to meet the requirements of the medical device, packaging system or sterilization process.

g) Materials shall not contain or release substances known to be toxic in sufficient quantity to cause a health hazard either before, during or after sterilization under the conditions of use.

h) Materials shall have microbial barrier properties which are consistent with the specified acceptance criteria unless they meet the criterion of impermeability when evaluated as per Annex C.

5.1.8 In addition to the requirements given in 5.1.1 through 5.1.7, adhesive-coated materials shall meet the requirements listed below.

a) Coating patterns shall be continuous without skips or breaks in the pattern sufficient to cause a discontinuity in the seal.

b) Coating mass shall be consistent with the stated value.

c) Materials shall demonstrate minimum specified seal strength when a seal is formed with another specified material under specified conditions.

5.1.9 In addition to the requirements given in 5.1.1 through 5.1.7 and, if appropriate, 5.1.8, sterile barrier systems and preformed sterile barrier systems shall meet the requirements listed below.

a) Sterile barrier systems and preformed sterile barrier systems shall meet the requirements of ISO 11607-2.

b) Materials and components, e.g. coatings, ink or chemical indicators, shall not adversely affect the medical device by reaction, contamination and/or transfer before, during or after the defined sterilization process.

c) If formed by sealing, the specified requirements for seal width and seal strength shall be met.

d) Peel-open characteristics shall be continuous and homogeneous, without delamination or tearing of the material that can affect aseptic opening and presentation.

NOTE If seals are not intended to be opened for aseptic presentation, a maximum seal strength limit is usually not necessary.

e) Once formed, the sterile barrier system shall provide seal integrity and/or closure integrity until it is opened at the point of use.

f) Opening a seal or a closure should be irreversible or destructive. If the open seal or closure is reversible, it shall be clearly evident that the seal or closure has been opened.

5.1.10 For reusable sterile barrier systems, e.g. containers and woven textile wraps, it shall be determined if processing in accordance with the provided instruction leads to a degradation that will limit the service life.

a) If degradation is anticipated, the labelling shall state the number of reprocessing cycles that can be tolerated, unless the end of the service life is detectable. This can be done in the form of stating how many times the sterile barrier system can be reused based on testing, or in the form of stating a performance test method prior to use, or in the form of stating a recommended visual inspection along with acceptance or failure criteria (e.g. unacceptable deterioration such as corrosion, discoloration, pitting, cracked seals).

b) It shall be determined that the minimum performance characteristics are maintained throughout the stated service life of the reusable sterile barrier system when following the recommended processing and sterilization instructions.

5.1.11 In addition to the requirements given in 5.1.1 through 5.1.7 and 5.1.10, reusable containers shall meet the requirements given below.

a) The container shall be fitted with a tamper-evident system to provide a clear indication when the closure integrity has been compromised.

b) The sterilizing agent port shall provide a barrier to microorganisms during removal from the sterilizer, transport and storage (see 5.2).

c) After forming the sterile barrier system, the closure shall provide a barrier to microorganisms until it is opened at the point of use.

d) The container shall be constructed to facilitate inspection of all essential parts.

e) Acceptance criteria shall be established for inspection prior to each reuse.

NOTE 1 Visual inspection is the most common procedure.

f) Individual components of the same container models shall be either completely interchangeable or designed such that the components cannot be interchanged.

NOTE 2 Suitable coding and/or labelling can address this design requirement.

g) Service, cleaning procedures and the manner of inspection, maintenance and replacement of components shall be specified.

NOTE 3 For additional guidance on reusable containers, see EN 868-8, ANSI/AAMI ST77 and ISO/TS 16775.

5.1.12 In addition to the requirements given in 5.1.1 through 5.1.7 and, if appropriate, 5.1.8, reusable woven textile wraps shall meet the requirements given below.

a) Performance requirements shall be met after any repairs to the material including qualifying the compatibility of the repair to the recommended processing and sterilization instructions.

b) Processing procedures for laundering and refurbishing shall be established and documented and ensure that performance requirements shall continue to be met.

NOTE Visual inspection is the most common procedure.

c) Processing procedures shall conform to the product labelling.

5.2 Microbial barrier properties

5.2.1 If not a declared porous material, the impermeability shall be determined in accordance with Annex C.

NOTE The microbial barrier properties of materials used in the construction of sterile barrier systems are critical for ensuring integrity and product safety. The methods used for evaluation of the microbial barrier properties are divided into two categories: those that are appropriate for impermeable materials, and those that are appropriate for porous materials.

5.2.2 A demonstration that the material is impermeable shall satisfy the microbial barrier requirement.

5.2.3 Porous materials shall provide an adequate microbial barrier to microorganisms.

NOTE Evaluation of the microbial barrier properties of porous materials can be done by challenging samples with an aerosol of bacterial spores or particulates, under a set of test conditions which specify the flow rate through the material, microbial or particulate challenge to the sample, and duration of the test. The microbial barrier properties of the material, under these specified test conditions, are determined by comparing the extent of bacterial or particulate penetration through the material with the original challenge. Data from a validated physical test method that correlates with a validated microbiological challenge method are considered acceptable for determining the microbial barrier properties. For testing of microbial barrier, see Table B.1. (For further information, see ISO/TS 16775.)

5.3 Compatibility with the sterilization process

5.3.1 It shall be demonstrated that the materials and preformed sterile barrier system, and sterile barrier systems are suitable for use in the specified sterilization process(es), cycle parameters, and process limits.

NOTE Acceptable practice would assume that sterilization compatibility is determined using a sterilizer designed, constructed and operated in accordance with the requirements of the relevant national, International or European Standards. For example, see ANSI/AAMI ST79, ISO 11135, ISO 11137 (all parts), ISO 14937, EN 285, EN 13060, EN 1422 or EN 14180.

5.3.2 Determination of suitability for the intended purpose shall include consideration of material variations that will occur.

5.3.3 The performance of the materials shall be evaluated to ensure that the material performance remains within specified limits after exposure to all the specified sterilization processes. (See 5.1).

NOTE 1 Specified sterilization processes can include multiple exposures of the same or different sterilization processes.

NOTE 2 Where the product is enclosed by multiple wrappings or layers, different limits on material properties can be set for inner and outer layers.

NOTE 3 Determination of suitability can be carried out concurrently with validation of the sterilization process(es) to be used.

5.4 Labelling system

The labelling system shall

a) remain attached, intact and legible until the point of use,

b) be compatible with the materials, sterile barrier system and medical device during and after the specified sterilization process(es) and cycle parameters and shall not adversely affect the sterilization process, and

c) not be printed or written in ink of a type which can be transferred to the medical device nor react with the packaging material and/or system to impair the utility of the packaging material and/or system, nor change colour to an extent which renders the label illegible.

NOTE Labelling systems can take several forms, including printing or writing directly on the material and/or sterile barrier system, or labels consisting of another layer of material attached to the surface of the material and/or system by adhesion, fusion or other means.

5.5 Storage and transport of materials and preformed sterile barrier systems

Materials and preformed sterile barrier systems shall be transported and stored under conditions that ensure that the performance characteristics remain within specified limits (see 5.1).

NOTE This can be accomplished by

a) demonstrating retention of these characteristics under defined storage conditions, or

b) ensuring that storage and transport conditions remain within manufacturer's instructions.

6 Design and development for packaging systems

6.1 General

6.1.1 The packaging system shall be designed to minimize the safety risks and health risks to the user and patient under the intended specified conditions of use.

6.1.2 The sterile barrier system shall allow the product to be presented in an aseptic manner.

NOTE Aseptic presentation can be demonstrated by completing a usability evaluation (see Clause 7).

6.1.3 The packaging system shall provide physical protection in order to maintain integrity of the sterile barrier system.

6.1.4 The protective packaging, if included, shall provide physical protection to the sterile barrier system and its contents.

6.1.5 The sterile barrier system and, if applicable, the protective packaging shall allow for sterilization and be compatible with the chosen process(es).

6.1.6 A terminally sterilized sterile barrier system with its protective packaging, if included, shall be designed to, maintain sterility through exposure to expected conditions and hazards during the specified processing, storage, handling, and distribution until that SBS is opened at the point of use or until the expiry date.

6.1.7 Maintenance of sterile barrier integrity may be used to demonstrate maintenance of sterility.

NOTE 1 See ANSI/AAMI ST65 and Reference [21]. The loss of sterility is regarded as event-related rather than time-related.

NOTE 2 There are different ways of demonstrating maintenance of sterility. For a sterile barrier system that retains a specified minimum pressure differential compared to atmospheric pressure after sterilization until the moment of intended use, it is acceptable to conclude that the sterile barrier system maintains sterile barrier integrity.

6.1.8 If the packaging system to be opened at the point of use consists of more than one packaging layer, the sterile barrier system(s) shall have an indication to be recognized as such.

NOTE 1 Symbols and guidance are included in Annex E.

NOTE 2 At the time of publication of this document, appropriate symbols were not yet available in ISO 15223-1.

6.1.9 When similar medical devices use the same packaging system, a rationale for establishing similarities and identifying the worst-case configuration shall be recorded. As a minimum, the worst-case configuration shall be used to determine conformity with this document.

NOTE For example, similarity could be established by different sizes of the same medical device.

6.2 Design

6.2.1 Procedures for the design and development of packaging systems shall be established, documented, implemented and maintained.

6.2.2 The selection and qualification of appropriate materials and preformed sterile barrier systems shall consider at a minimum the properties evaluated under Clause 5.

6.2.3 The design and development of a package system shall consider many factors that include, but are not limited to, the following:

a) user requirements and user environment;

b) the mass and configuration of the product;

c) the presence of sharp edges or protrusions;

d) the need for physical and other protection;

e) the sensitivity of the product to particular risks, e.g. radiation, moisture, mechanical shock, static discharge;

f) the number of items per packaging system;

g) package labelling requirements;

h) environmental limitations;

i) expiry date limitations of the product;

j) distribution and handling environment;

k) storage environment;

l) sterilization compatibility and residuals.

6.2.4 The medical device components and constructions that constitute sterile fluid-path closure assemblies shall be identified and specified. These should include, but are not limited to, the following:

a) materials;

b) finish;

c) component dimensions;

d) assembly dimensions (e.g. tolerances for interference fits).

6.2.5 Sterile fluid path products placed inside protective packaging that looks like a sterile barrier system shall indicate the protective packaging is not a sterile barrier system.

7 Usability evaluation for aseptic presentation

7.1 A documented usability evaluation shall be conducted to demonstrate that the sterile contents can be aseptically removed from the sterile barrier system for presentation.

7.2 The usability evaluation for aseptic presentation shall include an assessment of

a) the ability to identify where to begin opening,

b) the ability to recognize and perform the technique required to open the sterile barrier system without contaminating or damaging the contents, and

c) the ability to subsequently present the contents aseptically.

NOTE 1 It is best practice for this evaluation to consider conditions of use, including utilizing personal protective equipment as applicable (e.g. gloves and gowns).

NOTE 2 Sterile barrier systems require a presentation technique where contact of the presented sterile contents with the opened seal or closure is avoided to reduce the risk of contamination of the sterile contents by the external edge of the seal or closure which is not sterile.

NOTE 3 Sterile barrier systems require a presentation technique where exposure of presented sterile contents to potential contaminants (e.g. airborne particles, dust, etc.) is minimized.

7.3 The evaluation may be done under real or simulated conditions of use.

7.4 Usability evaluations may be leveraged between sterile product families and packaging families based on worst-case considerations or other valid rationales.

7.5 If the usability evaluation does not meet the three steps in 7.2, then either the sterile barrier system may be redesigned and/or additional information provided to the user. The ability to successfully open and present the contents shall then be evaluated in a subsequent usability evaluation.

NOTE As part of (or prior to) the usability evaluation, it can be useful to perform formative studies, where users are observed exploring a sterile barrier system and its opening features without guidance. It can also be useful to perform summative studies on designs which can be placed into the marketplace, the objective of which is to observe if the persons opening the package use the opening features in the way in which they were intended, or employ other means of accomplishing opening and presentation. (For further information see FDA guidance[27] and IEC 62366 series.)

8 Packaging system performance and stability

8.1 General

Sterile barrier system integrity testing (used to establish the capability of the sterile barrier system to maintain sterility) shall be performed after packaging system performance testing and stability testing on sterilized samples.

Sterile barrier system integrity testing may be performed by testing the integrity of the materials and the integrity of the seals and closures separately.

NOTE 1 The loss of sterility is regarded as event-related rather than time-related. For additional information, see ISO/TS 16775, ANSI/AAMI ST65, and Reference [21].

NOTE 2 Stability testing and performance testing are separate entities. Performance testing evaluates the interaction between the packaging system and the products in response to the stresses imposed by the manufacturing and sterilization processes and the handling, storage and shipping environment.

8.2 Packaging system performance testing

8.2.1 The packaging system shall provide adequate protection to all sterile barrier systems and the sterile contents through the hazards of handling, distribution and storage.

NOTE 1 These hazards can include, but are not limited to, the following:

a) shock and vibration;

b) compression;

c) temperature;

d) humidity;

e) mode of transportation;

f) pressure changes.

NOTE 2 Protective packaging is adequate when the sterile barrier system passes integrity testing. However, contained product functionality can be assessed separately.

8.2.2 Performance testing shall be conducted on packaging systems comprised of the worst-case sterile barrier system as well as the worst-case protective packaging.

NOTE It is not necessary to redo performance testing when new sealing equipment with equivalent sealing technology is introduced, provided the sealing process is validated, and capable of producing seals that meet the specifications of the packaging which was used for the prior documented performance testing (see also ISO/TS 16775).

8.2.3 A rationale for identifying the worst-case sterile barrier system shall be established and documented.

NOTE Worst-case considers exposure to all the specified sterilization processes and most challenging contents.

8.3 Stability testing

8.3.1 Stability testing shall demonstrate that the sterile barrier system maintains integrity over time.

8.3.2 Stability testing shall be performed using real-time aging.

8.3.3 Stability testing, using accelerated aging protocols, shall be regarded as sufficient evidence for claimed expiry dates until data from real-time aging studies are available.

8.3.4 If accelerated aging is conducted, it shall begin within three months of real-time aging, unless an alternative rationale has been developed. Real-time aging shall be started prior to commercialization.

8.3.5 If accelerated aging tests are performed, a rationale for the accelerated aging conditions and test duration chosen shall be established.

8.3.6 Unless it is demonstrated that the contents adversely interact with the sterile barrier system, then previously documented testing shall be sufficient.

NOTE In a similar way, it is not necessary to redo stability testing when new sealing equipment with similar sealing technology is introduced, provided the sealing process is validated and capable of producing seals that meet the specifications of the packaging which was used for the prior documented stability testing.

9 Packaging system validation and changes

9.1 Packaging systems that meet the requirements of design, usability, performance testing and stability testing shall be considered validated if the sterile barrier system conforms with ISO 11607-2.

9.2 Documents concerning packaging system designs shall be covered by a change control procedure for documenting, verifying and authorizing change.

9.3 Packaging systems shall be revalidated if changes are made to the design, contents, packaging materials, or configurations that compromise the original validation and can affect the integrity of the sterile barrier system. Packaging systems shall be revalidated if changes to the storage, handling and distribution hazards exceed those applied during the original validation.

NOTE The following list gives examples of changes that can affect the status of a validated packaging system:

— introduction of new packaging materials;

— raw material changes that can negatively impact the material properties or the stability;

— sterilization process changes;

— different shipping configurations or methods of distribution;

— market feedback of sterile barrier system integrity issues.

9.4 The need for revalidation shall be evaluated and recorded. If the situation does not require that all aspects of the original validation be repeated, this revalidation does not have to be as extensive as the initial validation.

NOTE It is acceptable practice to keep design validation separate from process validation to allow for targeted root cause analysis in case of issues and to limit the effort of revalidation to only those aspects that are really affected.

9.5 Minor design changes shall be recorded and can require review of the validation status.

NOTE Multiple minor changes are considered to be able to cumulatively affect the validation status of the packaging system.

10 Inspection immediately prior to aseptic presentation

It is best practice to visually inspect all sterile barrier systems, that are labelled as sterile, immediately prior to use in order to determine if breaches in sterile barrier system integrity are evident. When user-specific instructions for use for a sterile medical device are appropriate or required, these shall include instructions to visually inspect for breaches of packaging integrity prior to use.

11 Information to be provided

Information to be supplied with the material, preformed sterile barrier system or sterile barrier systems which are placed into health care markets can include, but is not limited to, the following:

— the name or trade name and address of the manufacturer and/or the manufacturer's authorized representative;

— the type, size or grade;

— batch number or other means of tracing the manufacturing history;

— the intended sterilization process(es) and processing methods;

— the expiry date, if applicable;

— any specific storage conditions, if applicable;

— any known restrictions on handling or use (e.g. environmental conditions), if applicable;

— whether the materials and/or preformed sterile barrier systems are intended for single use or reuse;

— for reusable materials and/or reusable preformed sterile barrier systems, instructions for use including the frequency and nature of maintenance, laundering and/or cleaning, sterilization, inspection for damage or wear;

— if instructions for use are supplied, the date of issue or revision.

Annex A
(informative)

Guidance on medical packaging

A.1 Factors influencing the choice of the materials and design of the packaging system

The specific nature of the medical device, the intended sterilization methods(s), and the intended use, expiry date, transport and storage all influence the packaging system design and choice of materials. Choosing appropriate materials for terminally sterilized medical device packaging systems is influenced by the inter-relationships that are illustrated in Figure A.1.

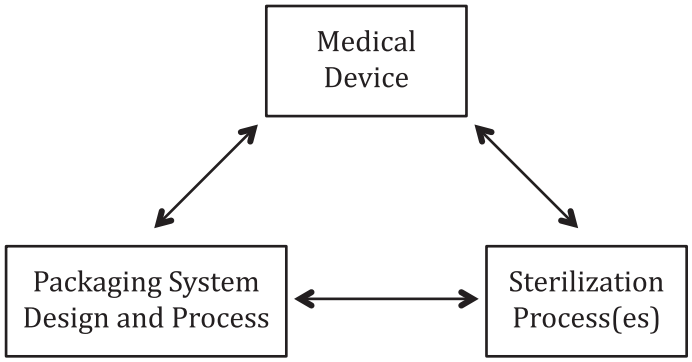


Figure A.1 — Inter-relationships influencing the choice of appropriate materials for terminally sterilized medical packaging systems

A.2 Sterilization processes and considerations

A.2.1 The choice of sterilization processes include, but is not limited to, ethylene oxide (EO), gamma irradiation (γ), electron beam (e-beam), moist heat and low-temperature oxidative sterilization processes. The manufacturer of a medical device chooses the appropriate sterilization processes for each device and their choice is dependent upon several factors. If the device is constructed of materials that are not irradiation stable, EO, moist heat and oxidizing agents are typically used. Alternatively, if a device tends to retain high residual concentrations of EO, the device manufacturer might choose irradiation.

A.2.2 If the device is intended to be sterilized by EO, moist heat or oxidizing processes, the sterile barrier system allows the sterilizing agents to enter, kill the microorganisms, and escape without significant residual concentrations.

A.2.3 If the device is to be sterilized by irradiation (γ or e-beam), a permeable component may not be required and the sterile barrier system can be made entirely of impermeable materials.

A.3 Sterile barrier systems

A.3.1 Sterile barrier systems for medical devices can have many characteristics in common. The majority have a top web, a bottom web and a means to join the webs together. In the case where a peelable seal is required, a sealant layer is applied to allow heat-sealing of the two layers together. The sealant layer, which is commonly known as coating, has traditionally been applied to the permeable web.

Today, many films incorporate the sealant layer as (a) layer(s) in the film construction. Where a weld seal is required, compatibility of the webs is required to allow joining by heat, or other methods such as ultrasonic welding.

A.3.2 There are many types and variations of sterile barrier systems used to package sterile medical devices. The first type is the preformed rigid tray with a die-cut lid. The tray is usually preformed by a thermoforming or pressure-forming process. The die-cut lid can be porous or impermeable and typically will have a sealant layer used to heat-seal the lid to the tray. Rigid trays with die-cut lids are commonly used for large profile and heavy devices, such as orthopaedic implants and pacemakers, as well as surgical kits.

A.3.3 The second type is the flexible peel pouch. A pouch is typically constructed of a film on one side and either film, paper or nonwoven on the other. Pouches are typically supplied as preformed sterile barrier systems where all the seals have been formed except for one (typically at the bottom). This remains open so that the device can be placed inside and then the final seal applied prior to sterilization. Vast arrays of different medical devices use pouches as the sterile barrier system, due to their wide availability in a variety of sizes. These devices are typically low profile and lightweight. Pouches can come with a variety of design features. (For example, gussets may be included to allow for higher profile devices.)

A.3.4 The third type is the sterilization bag. A sterilization bag is constructed from a single web of porous medical-grade paper that has been folded to form a long tube with or without side gussets. The tube is sealed along its length by a double line of adhesive. It is then cut to the required size and one end is sealed by one or more applications of adhesive. Additional folds may also be used to further strengthen the closure. The open end normally has either a lip or a thumb cut to facilitate ease of opening. Final closure of the bags is applied prior to sterilization.

A.3.5 The fourth type is the header bag. The header bag is primarily a welded seal bag fabricated from two impermeable but compatible film webs. One of the webs is usually offset. Across this offset area, a permeable material, with adhesive, is heat-sealed. This permeable material can later be peeled off allowing access to the interior of the bag. Header bags are popular for bulky items such as kits.

A.3.6 The fifth type is the process known as form/fill/seal (FFS). The sterile barrier systems that are manufactured via FFS can look just like pouches, rigid trays with lids or can have a flexible film bottom web that has been drawn or shaped. In FFS, the top and bottom web materials are placed on the FFS machine. The machine manufactures the sterile barrier system by forming the bottom web, filling the form with the device, and applying the top web and sealing the sterile barrier system.

A.3.7 The sixth type is the four-side-sealing (4SS) process. 4SS is a non-stop packaging process like flowpack. Most commonly it employs rotary sealing equipment to form the seal. In the 4SS process, the bottom and top webs are placed on the 4SS machine. The product is placed onto the bottom web. The top web is applied above it and, finally, all four sides are sealed. 4SS is used for packaging of gloves and wound-care products, for instance.

A.3.8 The above list of sterile barrier systems is not meant to be all inclusive. Other constructions can be acceptable as sterile barrier systems.

A.3.9 Medical devices with a sterile fluid path may use unique sterile fluid-path packaging systems directly affixed to the device fluid-path access points. These can consist of caps, plugs, covers or other device-specific closure designs. In these cases, the primary layer of product packaging may be represented by one of the four styles discussed above, but may not be required to provide a microbial barrier for the devices.

A.3.10 Health care facilities typically use sterile barrier systems in the form of pouches, reels, paper bags, sterilization wrap or reusable containers.

A.3.11 Sterilization wrap is used to provide a sterile barrier system for many devices sterilized in health care facilities. Instead of forming a heat or adhesive seal, the wrapping and folding process provides a tortuous path that maintains sterility. Devices are typically contained in organizing instrument trays prior to wrapping and subsequent sterilization.

A.3.12 Reusable containers are constructed of metal or synthetic polymeric materials capable of withstanding repeated exposures to hospital sterilization cycles. These containers typically have matched tops and bottoms with a gasket that provides an impervious seal between the two parts. A venting system allows the sterilizing agents to enter and escape from the container. The vent design and materials used for providing microbial filtration vary widely. Devices sterilized in containers can require specific preconditioning or a longer exposure time to ensure that the sterilization process is complete.

A.3.13 Terminal sterilization and sterility maintenance are essential for patient safety, irrespective of the facility that conducts these processes.

Annex B
(informative)

Standardized test methods, guides and procedures that can be used to demonstrate conformity with the requirements of this document

B.1 General

The following documents contain provisions that may be used to demonstrate conformity with provisions of this document. When using test methods and procedures listed in Table B.1, it is important to note the date of issue of these documents. Specific requirements for the use of test methods are found in 4.4.

The criteria for inclusion of test methods and procedures given in Table B.1 are that they shall be nominated for inclusion and commercially available from a standards development organization, trade association or national standards body. Consequently, the Bibliography contains additional test methods that were published in the literature. This annex is not intended to be all-inclusive and the development of new test methods is known to be underway at the time of publication.

B.2 Packaging materials and preformed sterile barrier systems

Table B.1 — Test methods and their status

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/ or bias	Guidance, Standard Practice
Accelerated aging	ASTM F1980	Standard guide for accelerated aging of sterile barrier systems for medical devices	NA[a]	NA	Yes
	EN 868–8	Packaging for terminally sterilized medical devices — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 —Requirements and test methods	NA	NA	Yes
Air permeance	ISO 5636-3	Paper and board — Determination of air permeance (medium range) — Part 3: Bendtsen method	No	No	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
	ISO 5636-5	Paper and board — Determination of air permeance and air resistance (medium range) — Part 5: Gurley method	No	No	NA
	JIS P-8117	Paper and board — Determination of air permeance and air resistance (medium range) — Gurley method	Yes	—	NA
	ASTM D737	Standard test method for air permeability of textile fabrics	Yes	—	NA
	ASTM F2981	Standard test method for verifying non-porous flexible barrier material resistance to the passage of air	No	Yes	NA
	TAPPI T460	Air resistance of paper (Gurley method)	Yes	—	NA
	TAPPI T536	Resistance of paper to passage of air (high-pressure Gurley method)	Yes	—	NA
Alcohol repellency	AATCC-193	Aqueous liquid repellency: water/alcohol solution resistance test	No	No	NA
Basis weight	ISO 536	Paper and board — Determination of grammage	No	No	NA
	JIS P-8124	Paper and board — Determination of grammage	No	No	NA
	ASTM D4321	Standard test method for package yield of plastic film	Yes	—	NA
	ASTM D3776–6M	Standard test methods for mass per unit area (weight) of fabric	Yes	—	NA
	TAPPI T410	Grammage of paper and paperboard (weight per unit area)	Yes	—	NA
Biocompatibility	ISO 10993-1 (JIS T-0993-1)	Biological evaluation of medical devices — Part 1: Evaluation and testing	NA	NA	Yes
	ASTM F2475	Standard guide for biocompatibility evaluation of medical device packaging materials	NA	NA	Yes
Burst	ISO 2758	Paper — Determination of bursting strength	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
	JIS P-8112	Paper — Determination of bursting strength	Yes	—	NA
	TAPPI T403	Bursting strength of paper	Yes	—	NA
	ASTM F1140	Standard test methods for internal pressurization failure resistance of unrestrained packages	Yes	—	NA
	ASTM D3786	Standard test method for bursting strength of textile fabrics — Diaphragm bursting strength tester method	Yes	—	NA
	ASTM F2054	Standard test method for burst testing of flexible package seals using internal air pressurization within restraining plates	Yes	—	NA
Chlorides	ISO 9197	Paper, board and pulps — Determination of water-soluble chlorides	—	Yes	NA
	JIS P-8144	Paper, board and pulps — Determination of water-soluble chlorides	Yes	—	NA
	TAPPI T 256	Water-soluble chlorides in pulp and paper	—	Yes	NA
	EN 868–4	Packaging for terminally sterilized medical devices — Part 4: Paper bags — Requirements and test methods (Annex B: Method for the determination of pH value, chloride and sulfate in paper bags)	No	No[c]	NA
Cleanliness	TAPPI T 437	Dirt in paper and paperboard	Yes	—	NA
	TAPPI T 564	Transparent chart for the estimation of defect size	No	No	NA
	JIS P-8145	Paper and board — Estimation of contraries	No	Yes	NA
Coat weight	ASTM F2217	Standard practice for coating/ adhesive weight determination	NA	NA	Yes
Conditioning	ISO 187	Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples	NA	NA	Yes

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/ or bias	Guidance, Standard Practice
	JIS P-8111	Paper, board and pulps — Standard atmosphere for conditioning and testing	NA	NA	Yes
	ASTM D4332	Standard practice conditioning containers, packages or packaging components for testing	NA	NA	Yes
	ISO 2233	Complete, filled transport packages and unit loads — Conditioning for testing	NA	NA	Yes
Dimensions	ASTM F2203	Standard test method for linear measurement using precision steel rule	Yes	—	NA
Drapability	ISO 9073-9	Textiles — Test methods for nonwovens — Part 9: Determination of drape coefficient	No	No	NA
	ISO 2493-1	Paper and board — Determination of bending resistance — Part 1: Constant rate of deflection	Yes	—	NA
	ISO 2493-2	Paper and board — Determination of bending resistance — Part 2: Taber-type tester	Yes	—	NA
	DIN 53121	Testing of paper and board — Determination of the bending stiffness by the beam method	No	No	NA
	TAPPI T489	Bending resistance (stiffness) of paper and paperboard (Taber-type stiffness tester in basic configuration)	Yes	—	NA
	TAPPI T566	Bending resistance (stiffness) of Paper (Taber-type tester in 0 to 10 Taber stiffness unit configuration)	Yes	—	NA
Flexural durability	ASTM F392	Standard test method for flex durability of flexible barrier materials	Yes	—	NA
Microbial barrier	ASTM F1608	Standard test method for microbial ranking of porous packaging materials (Exposure chamber method)	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
	DIN 58953–6	Sterilization — Sterile supply — Part 6: Microbial barrier testing of packaging materials for medical devices which are to be sterilized; subclause 3: Testing for germ proofness in moisture and subclause 4: Testing for germ proofness with passage of air	Yes	—	NA
	ASTM F2101	Test method for evaluating the bacterial filtration efficiency (BFE) of medical face masks materials, using a biological aerosol of staphylococcus aureus	—	Yes	NA
	SS 876 0019	Health care textiles — Bacterial penetration — Wet	No	No	NA
Microbial barrier surrogate	ASTM F2638	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier	Yes	—	NA
	BS 6256	Specification for paper for steam sterilization paper bags, pouches and reels for medical use Annex C: Methods for determination of methylene blue particulate penetration	No	No	NA
Oxygen permeance	ASTM D3985	Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using a Coulometric Sensor	Yes	—	NA
	ASTM F1307	Standard Test Method for Oxygen Transmission Rate Through Dry Packages Using a Coulometric Sensor	Yes	—	NA
	ASTM F1927	Standard Test Method for Determination of Oxygen Gas Transmission Rate, Permeability and Permeance at Controlled Relative Humidity Through Barrier Materials Using a Coulometric Detector	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/ or bias	Guidance, Standard Practice
	ASTM F2622	Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheeting Using Various Sensors	Yes	—	NA
Peel-open characteristic	EN 868–5	Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods (Annex E: Determination of peel characteristics of paper/plastic laminate products)	No	No	NA
Performance testing	ASTM D4169	Standard practice for performance testing of shipping containers and systems	NA	NA	Yes
	ISTA 3A&3B	International Safe Transit Association Preshipment Test Procedures	NA	NA	Yes
	ISTA 4A&4B	Packaged — product for shipment in known distribution channels	NA	NA	Yes
	ISTA 7D	Thermal controlled transport packaging for parcel delivery system shipment	NA	NA	Yes
	ISO 4180	Packaging — Complete, filled transport packages — General rules for the compilation of performance test schedules	NA	NA	Yes
	EN 868–8	Packaging for terminally sterilized medical devices — Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods	No	No	NA
	ASTM F2825	Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery	NA	NA	Yes
	ASTM D7386	Standard Practice for Performance Testing of Packages for Single Parcel Delivery Systems	NA	NA	Yes

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
pH	ISO 6588-1 (JIS P-8133)	Paper, board and pulps — Determination of pH of aqueous extracts — Part 1: Cold extraction	Yes	—	NA
	ISO 6588-2 (JIS P-8133)	Paper, board and pulps — Determination of pH of aqueous extracts — Part 2: Hot extraction	Yes	—	NA
	TAPPI T509	Hydrogen ion concentration (pH) of paper extracts (cold extraction method)	Yes	—	NA
	TAPPI T435	Hydrogen ion concentration (pH) of paper extracts (hot extraction method)	Yes	—	NA
Pore size	EN 868–2	Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods (Annex C: Method for the determination of pore size[d])	No	No[c]	NA
Printing and coating	ASTM F2250	Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials	NA	NA	Yes
	ASTM F2252	Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape	NA	NA	Yes
Puncture	ASTM D1709	Standard test method for impact resistance of plastic film by free-falling dart method	Yes	—	NA
	ASTM F1306	Standard test method for slow rate penetration resistance of flexible barrier films and laminates	Yes	—	NA
	ASTM D3420	Standard test method for pendulum impact resistance of plastic film	Yes[e]	—	NA
Seal strength	ASTM F88/ F88M	Standard test method for seal strength of flexible Barrier materials	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
	EN 868–5	Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods	No	No	NA
Specification development	ASTM F2559/ 2559F	Standard Guide for Writing a Specification for Sterilizable Peel Pouches	NA	NA	Yes
	ASTM F99	Standard Guide for Writing a Specification for Flexible Barrier Rollstock Materials	NA	NA	Yes
	ASTM F17	Standard Terminology Relating to Flexible Barrier Packaging	NA	NA	Yes
	ASTM F2097	Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products	NA	NA	Yes
Static electricity	BS 6524	Method for determination of the surface resistivity of a textile fabric	No	No	NA
	ASTM D257	Standard Test Methods for DC Resistance or Conductance of Insulating Materials	—	Yes	NA
Sterile barrier seal integrity	ASTM F1929	Standard test method for detecting seal leaks in porous medical packaging by dye penetration	Yes	—	NA
	ASTM F1886/ F1886M	Standard test method for determining integrity of seals for medical packaging by visual inspection	Yes	—	NA
	ASTM F3004	Standard test method for evaluation of seal quality and integrity using airborne ultrasound	No[f]	No	No
Sterile barrier system integrity	ASTM F2228	Standard test method for non-destructive detection of leaks in medical packaging which incorporates porous barrier material by CO_2 tracer gas method	Yes	—	NA
	ASTM F3039	Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
	ASTM F2227	Standard test method for non-destructive detection of leaks in non-sealed and empty medical packaging trays by CO_2 tracer gas method	Yes	—	NA
	ASTM F2391	Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas	Yes	—	NA
	ASTM F2096	Standard test method for detecting gross leaks in packaging by internal pressurization (Bubble test)	Yes	—	NA
	ASTM F2338	Standard test method for non-destructive detection of leaks in packages by vacuum decay	Yes	—	NA
	ASTM D3078	Standard test method for determination of leaks in flexible packaging by bubble emission	Yes	—	NA
	ASTM F2095	Standard test methods for pressure decay leak test for flexible packages with and without restraining plates	Yes	—	NA
Sulfates	ISO 9198	Paper, board and pulps — Determination of water-soluble sulfates	—	Yes	NA
	TAPPI T255	Water-soluble sulfates in pulp and paper, Test Method	—	Yes	NA
	EN 868–4	Packaging for terminally sterilized medical devices — Part 4: Paper bags — Requirements and test methods (Annex B: Method for the determination of pH value, chloride and sulfate in paper bags)	No	No[c]	NA
Tear resistance	ASTM D1424	Standard test method for tearing strength of fabrics by falling-pendulum (Elmendorf-type) apparatus	Yes	No	NA
	ASTM D1922	Standard test method for propagation tear resistance of plastic film and thin sheeting by pendulum method	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
	ASTM D1938	Standard test method for tear-propagation resistance (trouser tear) of plastic film and thin sheeting by a single tear-method	Yes	—	NA
	JIS P-8116	Paper — Determination of tearing resistance — Elmendorf tearing tester method	Yes	No	NA
	ISO 1974	Paper — Determination of tearing resistance (Elmendorf method)	No	No	NA
Tensile properties	ISO 1924-2 (JIS P-8113)	Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method	Yes	—	NA
	ISO 1924-3	Paper and board — Determination of tensile properties — Part 3: Constant rate of elongation method (100 mm/min)	Yes	—	NA
	ASTM D882	Standard test method for tensile properties of thin plastic sheeting	Yes	—	NA
	ASTM D5034	Standard test method for breaking strength and elongation of textile fabrics (Grab test)	Yes	—	NA
	TAPPI T494	Tensile properties of paper and paperboard (using constant rate of elongation apparatus)	Yes	—	NA
Thickness/ Density	ISO 534	Paper and board — Determination of thickness, density and specific volume	Yes	—	NA
	JIS P-8118	Paper and board — Determination of thickness, density and specific volume	No	—	NA
	ASTM F2251	Standard test method for thickness measurement of flexible packaging materials	Yes	—	NA
	TAPPI T551	Thickness of Paper and Paperboard (Soft Platen Method)	Yes	—	NA
	TAPPI T411	Thickness (calliper) of paper, paperboard and combined board	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Table B.1 *(continued)*

Attribute/ Characteristics	Reference	Title of reference	Test method has statement of precision and/or bias, repeatability and reproducibility	Test method only has statement of precision and/or bias	Guidance, Standard Practice
Water resistance	ISO 811	Textile fabrics — Determination of resistance to water penetration — Hydrostatic pressure test	No	No	NA
	EDANA 170–1	Wet barrier — Mason Jar	No	No	NA
	ISO 535	Paper and board — Determination of water absorptiveness — Cobb method	Yes	—	NA
	AATCC-127	Water resistance: Hydrostatic pressure test	No	No	NA
	TAPPI T441	Water absorptiveness of sized (non-bibulous) paper, paperboard, and corrugated fiberboard (Cobb test)	Yes	—	NA
	EN 868–2	Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods (Annex C: Method for the water repellency [e])	No	No[c]	NA
Wet burst in wet condition	ISO 3689	Paper and board — Determination of bursting strength after immersion in water	No	No	NA
Wet tensile properties	ISO 3781	Paper and board — Determination of tensile strength after immersion in water	No	No	NA
	JIS P-8135	Paper and board — Determination of tensile strength after immersion in water	No	No	NA
	TAPPI T456	Tensile breaking strength of water-saturated paper and paperboard ("wet tensile strength")	Yes	—	NA

[a] NA — not applicable.

[b] "—" indicates that precision and bias is stated in the first column.

[c] For statement of precision, see Reference [26].

[d] The test methods for determination of the pore size and water repellency can also be found in the annexes of EN 868–3:2017, EN 868–6:2017 and EN 868–7:2017.

[e] ASTM standard has only statement of precision.

[f] Each material and/or package shall have its own repeatability and reproducibility study conducted.

Annex C
(normative)

Test method for resistance of impermeable materials to the passage of air

C.1 Impermeable materials for sterile barrier systems shall be tested for air permeance in accordance with ISO 5636-5.

Test criterion: After not less than 1 hour there shall be no visible movement of the cylinder, within the tolerance of ±1 mm.

NOTE For the purpose of ISO 11607-2 and this document, materials showing deviance greater ±1 mm are considered to be porous materials.

C.2 If other test methods are used for routine monitoring and production testing, these methods shall be validated against the reference test method (see C.1) for the material used.

NOTE Examples of test methods used for routine monitoring and production testing are listed in Annex B. Other methods for determining air permeance can be applicable.

Annex D
(informative)

Environmental aspects

The need to minimize the potential adverse impacts on the environment of any products and of their packaging that occur over the product life cycle is recognized and increasingly regulated around the world.

Over decades of development the current state-of-the-art sterile barrier solutions have contributed to the significant progress in the fight against hospital acquired infections. Sterilization and the maintenance of sterility together with the prevention of cross-infections are critical elements in patient care. In developed countries health care-associated infections (HAI) continue to be a major issue in patient safety and even more so in developing countries. While patient safety and maintaining sterility continue to be at the top of priorities, the goal of this annex is to encourage users to also include environmental considerations when designing sterile barrier solutions, with the objective to minimize the environmental impact.

Medical packaging systems, as with any other products, have an impact on the environment during all stages of their life-cycle, e.g. extraction of resources; consumption of raw materials, water and energy during production processes; emissions to water, soil and air; and distribution and storage methods. Furthermore, it includes the intended usage, i.e. aseptic presentation of the medical device, re-usage and the end-of-life treatment including final disposal. All these impacts can range from slight to significant and are important to investigate.

The use of “life-cycle thinking”, meaning consideration for all the environmental aspects of a product at all stages of its life-cycle, applied to a product when making packaging system design decisions can have a significant impact. For example, using less raw material for the production of packaging has the potential to reduce the environmental impact.

Packaging for terminally sterilized medical devices is designed to be non-toxic and non-irritating. It has no major detrimental impact on the local environment or human beings, as long as it is used as intended.

References [140] to [163] are a list of standards and guidelines that identify the basic environmental aspects, potential impacts, ways to minimize and control them and principles regarding environmental claims, labels and declarations.

Annex E
(informative)

Draft guidance on ways to differentiate a sterile barrier system from protective packaging

The purpose of this annex is to inform the reader of the status of efforts underway, at the time of the publication of this document, to address ways to differentiate a sterile barrier system from protective packaging. This process will take some time hence, several proposals are shown in this informative annex.

If symbols are ultimately used for this purpose, they will have to be proposed to ISO/TC 210/WG 3 and CEN CLC/TC 3 for consideration of inclusion of into ISO 15223-1 and standardized in ISO 7000. The symbols shown in this annex are not standardized in ISO 7000 and are not endorsed by ISO. When symbols for these meanings are standardized in ISO 7000 this annex will be withdrawn.

A packaging system is composed of the sterile barrier system and the protective packaging. In many cases, there is no difficulty differentiating the two. A corrugated outer shipping container is obviously not a sterile barrier system. However, there are circumstances where it is difficult to differentiate between a validated sterile barrier system (9.1) and protective packaging that looks like a sterile barrier system.

Sterile fluid path products such as tubing sets are covered in protective packaging made of materials that are often used in sterile barrier systems and as a result looks like an SBS. This outer covering has not been validated as an SBS and only the fluid path of the device is sterile. A misinterpretation by a user could be to introduce the contents of the protective covering to a sterile field contaminating the field by mistake.

Another example is when a sterile medical device is packaged within a rigid tray and lid (inner layer) that is inside a second rigid tray and lid (outer layer) which is common with orthopaedic implants. The device manufacturer may choose to only validate the outer layer as a sterile barrier system. This would allow aseptic transfer the inner layer containing the device to the sterile field where it would remain until opened to implant the contents. What happens if this implant is not needed due to a size error or interruption of the surgery? The inner layer looks just like a sterile barrier system but it has not been validated. This device cannot be placed back into storage and disposition should be managed according to the instructions for use (IFU). If the device manufacturer had validated each layer of SBS independently, the device could be placed back into storage.

The last example is the packaging system used for procedure kits. In the health care facility sterile processing department, these are often wrapped in sterilization wrap (also known as blue wrap) forming the sterile barrier system and sterilized. After cooling, they are placed inside a protective “dust cover” which is usually a film bag. However, medical device manufacturers make procedure kits which appear very similar but are completely different. They will wrap the kit in a layer of material which ultimately becomes the back-table cover. This material can appear to be like the sterilization wrap used by the health care facility. The wrapped kit is then placed into a “vent bag” which is a film bag with one or more vents covered with porous material to allow gas exchange to facilitate sterilization by ethylene oxide. In this case the medical device manufacturer will typically only validate the vent bag as the sterile barrier system.

The European Commission has published the new Medical Device Regulation and the new In Vitro Diagnostic Regulation on the 5th of May 2017. There are very specific requirements regarding “sterile packaging” which is really the sterile barrier system (SBS) as defined in this standard. The issue of identifying sterile barrier systems is addressed as follows:

"Medical Device Regulation Annex 1 — GENERAL SAFETY AND PERFORMANCE REQUIREMENTS — Chapter III

23.3. Information on the packaging which maintains the sterile condition of a device ('sterile packaging')

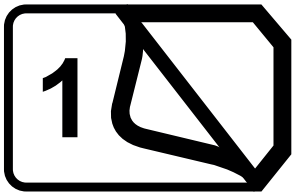
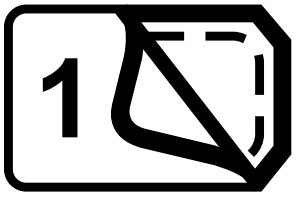
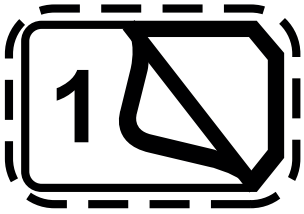
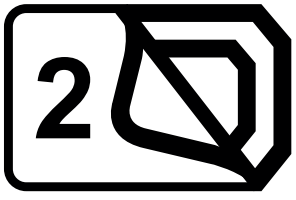
The following particulars shall appear on the sterile packaging:

(a) an indication permitting the sterile packaging to be recognized as such, ..."

ISO/TC 198/WG 7 (the working group responsible for this standard) has reviewed these clauses and agrees in general that there are packaging system configurations used today where it is difficult to differentiate between the sterile barrier system and protective packaging. This annex serves as an update on the status of activities to address this issue at the time of publication of this document.

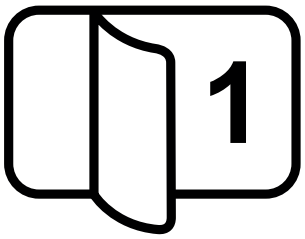
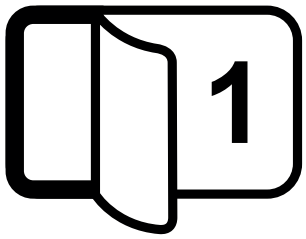
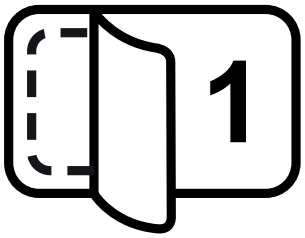
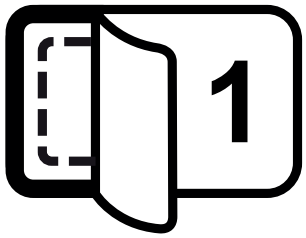
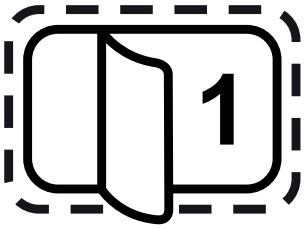
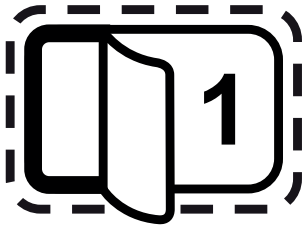
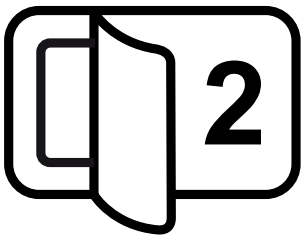
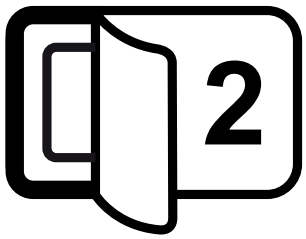
There have been proposals by the UK and the Sterile Barrier Association (SBA) on possible symbols that could be used to identify the sterile barrier system. The SBA has conducted a survey of proposed symbols that is available on www.sterilebarrier.org. This survey proposed the use of solid lines to denote a validated sterile barrier system and dashed lines to denote protective packaging (see Table E.1).

Table E.1 — Symbols used in the initial Sterile Barrier Association Survey

	Proposal 1 Use the abbreviation 'SBS' to indicate the sterile barrier system configuration	**Proposal 2** Use the form of a blister to indicate the sterile barrier system configuration
Solid line indicates sterile barrier material		
Dotted line indicates an additional inner packaging layer (which is not a validated SBS) to minimize the risk of contamination during aseptic presentation or indicates an outer protective packaging layer		
Configuration A: Sterile barrier system/sterile packaging		
Configuration B: Sterile barrier system with an additional packaging layer inside to minimize the risk of contamination during aseptic presentation		
Configuration C: Non-sterile protective packaging with sterile barrier system inside		
Configuration E: Double sterile barrier system		 2=two sterile barrier systems

The results of the survey indicate the solid and dashed lines are well understood once explained and that the preference is for a symbol that does not contain letter such as SBS. Based upon this initial survey, the SBA have compiled revised symbols for consideration from several sources (see Table E.2). These proposals also use numbers to indicate the number of sterile barrier systems.

Table E.2 — Example of revised symbol proposals resulting from the Sterile Barrier Association Survey

	Option 1	Option 2
Configuration A: Sterile barrier system/ sterile packaging		
Configuration B: Sterile barrier system with an additional packaging layer inside		
Configuration C: Non-sterile protective packaging with the sterile barrier system inside		
Configuration E: Double sterile barrier system		

A pouch containing a sterile medical device that has been validated as an SBS would receive the symbol shown in **Configuration A**.

For a sterile medical device that is contained within a rigid tray and lid (inner layer) that is inside a second rigid tray and lid (outer layer), if the device manufacturer chose to only validate the outer layer as a sterile barrier system the SBS would receive the symbol shown in **Configuration B**. If the device manufacturer chose to validate both the outer layer and inner layer as sterile barrier systems independently, the SBS would receive the symbol shown in **Configuration E**.

A sterile procedure kit medical device that is contained within sterilization wrap and subsequently covered with a film "dust cover" would receive the symbol shown in **Configuration C**.

Interestingly, the centre of the current debate is what shape the image takes in the symbol since there are so many configurations of sterile barrier systems such as pouches, header bags, trays, wrapped goods, etc.

The proposals shown in this annex are only draft proposals. The reader is advised to keep abreast of additional input from the SBA and the upcoming activities in ISO/TC 210/WG 3 and CEN CLC/TC 3. Ultimately the final proposal will have to be submitted to ISO/TC 145/SC 3 in order for them to assess and eventually register the symbols in ISO.

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[3] ISO 9001, *Quality management systems — Requirements*

[4] ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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[6] ISO 11137 (all parts), *Sterilization of health care products — Radiation*

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