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

ICS: 11.080.30
Contents

Foreword ........................................................................................................................................................................................................... v
Introduction ...................................................................................................................................................................................................... vii

1 Scope ........................................................................................................................................................................................................... 1
2 Normative references ........................................................................................................................................................................... 1
3 Terms and definitions .......................................................................................................................................................................... 1
4 General requirements ........................................................................................................................................................................ 5
  4.1 General .................................................................................................................................................................................................. 5
  4.2 Quality systems ................................................................................................................................................................................ 5
  4.3 Sampling .................................................................................................................................................................................................. 5
  4.4 Test methods .................................................................................................................................................................................. 5
  4.5 Documentation .............................................................................................................................................................................. 5
5 Materials, preformed sterile barrier systems and sterile barrier systems ........................................................................................................... 6
  5.1 General requirements ................................................................................................................................................................... 6
  5.2 Microbial barrier properties .......................................................................................................................................................... 9
  5.3 Compatibility with the sterilization process ................................................................................................................................... 10
  5.4 Labelling system ............................................................................................................................................................................. 10
  5.5 Storage and transport of materials and preformed sterile barrier systems ................................................................................... 10
6 Design and development for packaging systems ........................................................................................................................................ 11
  6.1 General .................................................................................................................................................................................................. 11
  6.2 Design .................................................................................................................................................................................................. 11
7 Usability evaluation for aseptic presentation .................................................................................................................................................. 12
8 Packaging system performance and stability ................................................................................................................................................ 13
  8.1 General .................................................................................................................................................................................................. 13
  8.2 Packaging system performance testing ......................................................................................................................................... 13
  8.3 Stability testing ................................................................................................................................................................................ 13
9 Design changes and revalidation ......................................................................................................................................................................... 14
10 Inspection of sterile medical devices packages immediately prior to aseptic presentation ........................................................................ 14
11 Information to be provided ......................................................................................................................................................................... 15
Annex A (informative) Guidance on medical packaging ...................................................................................................................................... 16
Annex B (informative) Standardized test methods, guides and procedures that may be used to demonstrate compliance with the requirements of this part of ISO 11607 ........................................................................................................ 19
Annex C (normative) Test method for defining impermeable materials to the passage of air ........................................................................ 30
Annex D (informative) Environmental aspects ................................................................................................................................................ 31

Annex ZC (informative) Relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered .....................................................41

Bibliography ............................................................................................................................................................................................................................43
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 on 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 the following URL: 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+Amd1:2014), which has been technically revised.

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

— Alignments of definitions following ISO 11139 to ensure harmonization throughout the standards under ISO TC198.
— Editorial changes, paragraph restructuring and rewrites for better flow of the document.
— New requirements for evaluation of usability for aseptic presentation.
— New requirements for inspection of sterile barrier system integrity prior to use.
— A new section with requirements for revalidation in line with ISO 11607-2.
— Annex B has been updated and various international test methods have been added or deleted.
— A new informative Annex D has been added with environmental considerations.
— A new informative Annex E has been added with guidance on the relationship of this standard with the general safety and performance requirements of the European MDR and IVDR.

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

This document (prEN ISO 11607-1:2017) has been prepared by Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.


This document has been prepared under a standardization request given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annexes ZA, B and C, which are an integral part of this document.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

<table>
<thead>
<tr>
<th>Normative references as listed in Clause 2 of the ISO standard</th>
<th>Equivalent dated standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO 5636-5</td>
<td>EN</td>
</tr>
<tr>
<td></td>
<td>ISO 5636-5:2013</td>
</tr>
</tbody>
</table>
Introduction

The process of designing and developing a packaging system for terminally sterilized medical devices is a complicated and critical endeavor. 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 part of ISO 11607 specifies requirements for design of sterile barrier systems and packaging systems for terminally sterilized medical devices, the basic attributes required of materials and preformed sterile barrier systems as well as design validation requirements. This International Standard is written as a general (horizontal) standard considering a wide range of potential materials, medical devices, packaging system designs, and sterilization methods and can be applied by suppliers of material, of preformed sterile barrier system, 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. Both parts of ISO 11607 were designed to meet the selected Essential Requirements of the European Medical Device Directives. During the revision of ISO 11607-1 and -2, the European Commission published the drafts and final versions of the European Medical Device Regulations (MDR) and the In Vitro Diagnostics Regulation (IVDR). The committee responsible for ISO 11607-1 and -2 incorporated changes in this revision to meet the specific requirements of the MDR and IVDR.

European standards that provide requirements for particular materials and preformed sterile barrier systems are available and known as the EN 868 series. Compliance with EN 868 Parts 2 to 10 can be used to demonstrate compliance with one or more of the requirements of this part of ISO 11607.

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 by this standard in 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 can be found 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 healthcare facilities for use in internal sterilization are considered as 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 part of ISO 11607 specifies the 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.

This part of ISO 11607 is applicable to industry, to health care facilities, and wherever medical devices are placed in sterile barrier systems and sterilized.

This part of ISO 11607 does not cover all requirements for sterile barrier systems and packaging systems for medical devices that are manufactured aseptically. Additional requirements might also be necessary for drug/device combinations.

This part of ISO 11607 does not describe a quality assurance system for control of all stages of manufacture.

This part of ISO 11607 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

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 http://www.iso.org/obp

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

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

[SOURCE: ISO/DIS 11139:2017]
3.3 closure
means used to close a sterile barrier system where no seal is formed

Note 1 to entry: For example, a sterile barrier system can be closed by a reusable container gasket or sequential folding to construct a tortuous path.

3.4 closure integrity
a characteristic of the closure which minimizes the risk of ingress of microorganisms demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage

3.5 expiry date
the date by which product should be used

3.6 labelling
label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device but excluding shipping documents

[SOURCE: ISO/DIS 11139:2017]

3.7 medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use or calibrator, software, material or other similar 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, 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: Modified from ISO/DIS 11139:2017]
3.8 **microbial barrier**
property of the sterile barrier system which minimizes the risk of ingress of microorganisms demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage

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

[SOURCE: ISO/DIS 11139:2017]

3.10 **packaging system**
combination of the sterile barrier system and protective packaging

[SOURCE: ISO/DIS 11139:2017]

3.11 **preformed sterile barrier system**
sterile barrier system (3.21) that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags, and open reusable containers

[SOURCE: ISO/DIS 11139:2017]

3.12 **product**
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), healthcare product(s)

Note 1 to entry: For the purpose of ISO 11607-1 and ISO 11607-2, product includes preformed sterile barrier systems, sterile barrier systems, and contents within them.

[SOURCE: Modified from ISO/DIS 11139:2017]

3.13 **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

3.14 **repeatability**
closeness of the agreement between the results of successive measurements of the same particular quantity subject to measurement (measurand) carried out under the same conditions of measurement

[SOURCE: ISO/DIS 11139:2017]

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

[SOURCE: ISO/DIS 11139:2017]

3.16 **reusable container**
rigid sterile barrier system designed to be repeatedly used
3.17 seal
result of joining surfaces together

Note 1 to entry: For example, surfaces can be jointed together by use of adhesives or thermal fusion.

3.18 seal integrity
a characteristic of the seal which minimizes the risk of ingress of microorganisms demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage

3.19 seal strength
mechanical capacity of the seal to withstand force

[SOURCE: ISO/DIS 11139:2017]

3.20 sterile
free from viable microorganisms

[SOURCE: ISO/DIS 11139:2017]

3.21 sterile barrier system
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/DIS 11139:2017]

3.22 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

Note 1 to entry: An example of sterile fluid-path packaging would be the interior of the tubing for administration of an intravenous fluid.

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

3.24 sterilizing agent
physical or chemical entity, or combination of entities having sufficient microbicidal activity to achieve sterility under defined conditions

[SOURCE: ISO/DIS 11139:2017]

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

3.26 useful life
period during which all the performance requirements are met

[SOURCE: ISO/DIS 11139:2017]
3.27 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.

4 General requirements

4.1 General
Practices in 4.2, 4.3, 4.4 and 4.5 are a fundamental prerequisite of demonstrating compliance to ISO 11607-1.

4.2 Quality systems

4.2.1 The activities described within this part of ISO 11607 shall be carried out within a formal quality system.

NOTE ISO 9001 and ISO 13485 contain requirements for suitable quality systems. Additional requirements might be specified by a country or region.

4.2.2 It shall not be necessary to obtain third-party certification of the quality system to fulfil the requirements of this part of ISO 11607.

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 might be specified by countries or regions. For further guidance, see ISO/TS 16775:2014, Annex L.

4.4 Test methods

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

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

NOTE Pass/fail is a type of acceptance criterion.

4.4.3 All test methods used to show compliance with this part of ISO 11607 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; and

— establishment of test method sensitivity for integrity tests.

4.5 Documentation

4.5.1 Demonstration of compliance with the requirements of this part of ISO 11607 shall be documented.

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

4.5.3 Documentation of compliance 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

Selection of suitable materials and/or preformed sterile barrier systems is a fundamental prerequisite for fulfilment of the goals of a terminally sterilized medical device packaging system.

NOTE 1 Compliance with one or more requirements of this part of ISO 11607 can be demonstrated by using one or more parts of the series EN 868-2 to EN 868-10.

NOTE 2 A confirmation of compliance to a part of EN 868 is not sufficient to be in full compliance with ISO 11607-1.

5.1.1 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 this subclause (5.1) are not intended to be all-inclusive. Materials which have characteristics not listed in this subclause may be evaluated using the performance criteria given in Clauses 6 and 7.

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 that:

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; and

c) the material and/or sterile barrier meets specification.
5.1.4 As a minimum, the following shall be considered:

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 part of ISO 11607.

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 16775:2014, A.3.3.
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 shelf-life limitations for pre-sterilization and 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 comply with established specific or minimum physical properties, such as tensile strength, thickness variation, tear resistance, air permeance and burst strength.
f) Materials shall comply with 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) 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.

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

c) 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.

d) Once formed, the sterile barrier system shall provide seal integrity and/or closure integrity.

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 useful life.

5.1.10.1 If degradation is anticipated, the number of reprocessing cycles that can be tolerated shall be stated in the product labelling, or the end of the useful life shall be 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).

5.1.10.2 It shall be determined that the minimum performance characteristics are maintained throughout the stated useful 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.

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 containers 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 for the finished device.

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 The impermeability of a material 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 Demonstrating 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 1 There is no universally accepted method of demonstrating microbial barrier properties. Evaluation of the microbial barrier properties of porous materials is typically conducted 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 further information, see Sinclair and Tallentire 2002, Tallentire and Sinclair 1998, Scholla et. al 1995, and Scholla et al. 2000, and ISO/TS 16775).

NOTE 2 Seals and closures have a requirement for microbial barrier, see 5.1.9 d) and 5.1.11 c).
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) and cycle parameters.

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

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 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.

5.3.3 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 might 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 might 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

5.5.1 Materials and preformed sterile barrier systems shall be protected to maintain their performance characteristics during transport and storage, via packaging or other methods.

NOTE Careful handling within a single health care facility in accordance with manufacturers’ instructions is considered adequate protection.

5.5.2 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, and

b) ensuring that storage conditions remain within specified limits.
6 Design and development for packaging systems

6.1 General

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.

6.1.1 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).

6.1.2 The packaging system shall provide physical protection and maintain integrity of the sterile barrier system.

6.1.3 The protective packaging, if included, shall provide physical protection to the sterile barrier system and the device.

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

6.1.5 The sterile barrier system shall maintain sterility until the point of use or until the expiry date.

NOTE See also 8.3.1.

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

NOTE 1 See ANSI/AAMI ST65: 2013 and Hansen et al. 1995. The loss of sterility is regarded as event-related rather than time-related.

NOTE 2 A sterile barrier system which retains a specified minimum pressure differential compared to atmospheric pressure after sterilization until the moment of intended use is considered to maintain sterile barrier integrity.

6.1.7 When similar medical devices use the same packaging system, a rationale for establishing similarities and identifying the worst-case configuration shall be documented. As a minimum, the worst-case configuration shall be used to determine compliance with this part of ISO 11607.

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

6.2 Design

6.2.1 There shall be documented procedures for the design and development of packaging systems.

6.2.2 The selection and qualification of appropriate materials and preformed sterile barrier systems shall consider as 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:

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 product components and constructions which constitute sterile fluid-path closure assemblies shall be identified and specified. These should include, but are not limited to:

a) materials,

b) finish,

c) component dimensions, and

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

6.2.5 The results of the design and development process shall be recorded, verified and approved prior to release of the product.

7 Usability evaluation for aseptic presentation

7.1 A documented usability evaluation shall demonstrate that the requirements for aseptic presentation can be met.

7.2 The usability evaluation for aseptic presentation shall include the location to begin opening, the opening technique of the sterile barrier system and subsequent aseptic presentation of the contents is clearly evident or information on opening and aseptic presentation is supplied in the instructions for use (IFU).

NOTE 1 The evaluation can be done in a real or simulated environment. Usability evaluation can be leveraged between product and packaging families based on worst case considerations or other valid rationales.

NOTE 2 Depending upon storage conditions and time, a SBS can have different levels of outside bioburden which can result in different risks for aseptic presentation as well as the cleanliness of the place of opening.

NOTE 3 Heat sealed SBS require a presentation technique where contact of the presented product to the peeled seal is avoided in order to avoid contamination of the sterile product with delaminated matter or possible unsterile particulates.

NOTE 4 Opened closures of reusable containers do not generate or present delaminated matter and may, like sterile product which is placed in silicone holders or silicone mats or which is equipped with silicone sharps protectors or corner protectors, be regarded as sterile.
8 Packaging system performance and stability

8.1 General

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

NOTE 1 SBS integrity testing is acceptably performed by testing the integrity of the materials and the integrity of the seals and closures.

NOTE 2 For additional information see ISO/TS 16775:2014, 3.2.3; ANSI/AAMI ST65: 2013; and Hansen et al. 1995[30].

NOTE 3 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):

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 SBS 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 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 (see also ISO/TS 16775).

8.2.3 A rationale for identifying the worst-case SBS shall be established and documented.

NOTE Worst-case would consider 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 Real-time and accelerated aging tests shall begin within three months of each other.

NOTE 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.

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

8.3.6 Unless it is demonstrated that the device interacts with the SBS, 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 Design changes and revalidation

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

9.2 Packaging systems shall be revalidated if changes are made to the design, product, packaging materials, configurations or specifications of storage, handling and distribution, which compromise the original validation and affect the integrity of packaging, sterility, safety or efficacy of sterile medical devices.

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

— introduction of new packaging materials;

— raw material changes that would 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.

9.3 The need for revalidation shall be evaluated and documented. 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.

9.4 Minor design changes shall be documented and may 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 of sterile medical devices packages immediately prior to aseptic presentation

10.1 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.
10.2 All sterile barrier systems labelled as sterile shall be visually inspected prior to use in order to determine if breaches in sterile barrier system integrity have occurred.

11 Information to be provided

11.1 National or regional regulations may require information to be supplied with the material, preformed sterile barrier system or sterile barrier systems which are placed into these healthcare markets; this information shall be provided.

NOTE This information includes (but is not limited to):

— 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 reprocessing 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, they shall contain 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 — Interrelationships 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 are not limited to, ethylene oxide (EO), gamma irradiation (γ), electron beam (e-beam), steam, and low-temperature oxidative sterilization processes. If the device is intended to be sterilized by EO, steam, or oxidizing processes, the sterile barrier system has a permeable component to allow the sterilizing gases to enter, kill the microorganisms, and escape without significant residual concentrations.

A.2.2 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. 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, steam, and oxidizing agents are typically used. Alternatively, if a device tends to retain high residual concentrations of EO, the device manufacturer may choose irradiation.

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 pre-formed rigid tray with a die-cut lid. The tray is usually performed 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 by several inches. 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 may 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 Healthcare 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 healthcare 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 agent gasses to enter and escape from the container. The vent design and materials used for providing microbial filtration vary widely. Devices sterilized in containers may 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 may be used to demonstrate compliance with the requirements of this part of ISO 11607

B.1 General

The following documents contain provisions that may be used to demonstrate compliance with provisions of this International Standard. 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 must 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

<table>
<thead>
<tr>
<th>Attribute/Characteristics</th>
<th>Reference</th>
<th>Title of reference</th>
<th>Test method has statement of precision and/or bias, repeatability and reproducibility</th>
<th>Test method only has statement of precision and/or bias</th>
<th>Guidance, Standard Practice</th>
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<td>Accelerated aging</td>
<td>ASTM F1980</td>
<td>Standard guide for accelerated aging of sterile barrier systems for medical devices</td>
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<td>EN 868–8</td>
<td>Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods</td>
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<td>Air permeance</td>
<td>ISO/TS 5636-2</td>
<td>Paper and board — Determination of air permeance (medium range) — Part 2: Schopper method</td>
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<td>ASTM D737</td>
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<td>ASTM F2981</td>
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<td>TAPPI T460</td>
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<td>TAPPI T536</td>
<td>Resistance of paper to passage of air (high-pressure Gurley method)</td>
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<td>Alcohol repellency</td>
<td>AATCC-193</td>
<td>Aqueous liquid repellency: water/alcohol solution resistance test</td>
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<td><strong>Basis weight</strong></td>
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<td><strong>Biocompatibility</strong></td>
<td>ISO 10993-1 (JIST-0993-1)</td>
<td>Biological evaluation of medical devices — Part 1: Evaluation and testing</td>
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<td>ASTM F2475</td>
<td>Standard guide for biocompatibility evaluation of medical device packaging materials</td>
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<td>Paper — Determination of bursting strength</td>
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<td>TAPPI T403</td>
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<td>ASTM F1140</td>
<td>Standard test methods for internal pressurization failure resistance of unrestrained packages</td>
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<td>ASTM F2054</td>
<td>Standard test method for burst testing of flexible package seals using internal air pressurization within restraining plates</td>
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<td><strong>Chlorides</strong></td>
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<td>JIS P-8144</td>
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<td>Water-soluble chlorides in pulp and paper</td>
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<td>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)</td>
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<td><strong>Cleanliness</strong></td>
<td>TAPPI T 437</td>
<td>Dirt in paper and paperboard</td>
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<td>TAPPI T 564</td>
<td>Transparent chart for the estimation of defect size</td>
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<td><strong>Coat weight</strong></td>
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<td>Standard practice for coating / adhesive weight determination</td>
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<td><strong>Conditioning</strong></td>
<td>ISO 187</td>
<td>Paper, board and pulps — Standard atmosphere for conditioning and testing and procedure for monitoring the atmosphere and conditioning of samples</td>
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<td>ASTM D4332</td>
<td>Standard practice conditioning containers, packages or packaging components for testing</td>
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<td>ISO 2233</td>
<td>Complete, filled transport packages and unit loads — Conditioning for testing</td>
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<td><strong>Dimensions</strong></td>
<td>ASTM F2203</td>
<td>Standard test method for linear measurement using precision steel rule</td>
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<td><strong>Drapability</strong></td>
<td>ISO 9073-9</td>
<td>Textiles — Test methods for non-wovens — Part 9: Determination of drape coefficient</td>
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<td>TAPPI T566</td>
<td>Bending resistance (stiffness) of Paper (Taber-type tester in 0 to 10 Taber stiffness unit configuration)</td>
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<td><strong>Flexural durability</strong></td>
<td>ASTM F392</td>
<td>Standard test method for flex durability of flexible barrier materials</td>
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<td><strong>Microbial barrier</strong></td>
<td>ASTM F1608</td>
<td>Standard test method for microbial ranking of porous packaging materials (Exposure chamber method)</td>
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<td>ASTM F2638</td>
<td>Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier</td>
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<td></td>
<td>DIN 58953–6</td>
<td>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</td>
<td>YES</td>
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<td>BS 6256</td>
<td>Specification for paper for steam sterilization paper bags, pouches and reels for medical use Appendix C: Methods for determination of methylene blue particulate penetration</td>
<td>NO</td>
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<td>ASTM F2101</td>
<td>Test method for evaluating the bacterial filtration efficiency (BFE) of medical face masks materials, using a biological aerosol of staphylococcus aureus</td>
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<td>YES</td>
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<td>SS 876 0019</td>
<td>Health care textiles — Bacterial penetration — Wet</td>
<td>NO</td>
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<td><strong>Oxygen permeance</strong></td>
<td>ASTM D3985</td>
<td>Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheet- ing Using a Coulometric Sensor</td>
<td>YES</td>
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<td>ASTM F2622</td>
<td>Standard Test Method for Oxygen Gas Transmission Rate Through Plastic Film and Sheet- ing Using Various Sensors</td>
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<tr>
<td>Peel-open characteristic</td>
<td>EN 868–5</td>
<td>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)</td>
<td>NO</td>
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<td>Performance testing</td>
<td>ASTM D4169</td>
<td>Standard practice for performance testing of shipping containers and systems</td>
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<td>ISTA 3A&amp;3B</td>
<td>International Safe Transit Association Preshipment Test Procedures</td>
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<td>ISTA 4A&amp;4B</td>
<td>Packaged – product for shipment in known distribution channels</td>
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<td>ISTA 7D</td>
<td>Thermal controlled transport packaging for parcel delivery system shipment</td>
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<td>ISO 4180</td>
<td>Packaging — Complete, filled transport packages — General rules for the compilation of performance test schedules</td>
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<td>EN 868–8</td>
<td>Packaging for terminally sterilized medical devices – Part 8: Re-usable sterilization containers for steam sterilizers conforming to EN 285 — Requirements and test methods</td>
<td>NO</td>
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<td>ASTM F2825</td>
<td>Standard Practice for Climatic Stressing of Packaging Systems for Single Parcel Delivery</td>
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<td>TAPPI T509</td>
<td>Hydrogen ion concentration (pH) of paper extracts (cold extraction method)</td>
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<td>TAPPI T435</td>
<td>Hydrogen ion concentration (pH) of paper extracts (hot extraction method)</td>
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<tr>
<td><strong>Pore size</strong></td>
<td>EN 868–2</td>
<td>Packaging for terminally sterilized medical devices – Part 2: Sterilization wrap – Requirements and test methods (Annex C: Method for the determination of pore size)</td>
<td>NO</td>
<td>NO&lt;sup&gt;b&lt;/sup&gt;</td>
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<td><strong>Printing and coating</strong></td>
<td>ASTM F2250</td>
<td>Standard Practice for Evaluation of Chemical Resistance of Printed Inks and Coatings on Flexible Packaging Materials</td>
<td>NA</td>
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<td>ASTM F2252</td>
<td>Standard Practice for Evaluating Ink or Coating Adhesion to Flexible Packaging Materials Using Tape</td>
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<td><strong>Puncture</strong></td>
<td>ASTM D1709</td>
<td>Standard test method for impact resistance of plastic film by free-falling dart method</td>
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<td>ASTM F1306</td>
<td>Standard test method for slow rate penetration resistance of flexible barrier films and laminates</td>
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<td>ASTM D3420</td>
<td>Standard test method for pendulum impact resistance of plastic film</td>
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<td><strong>Seal strength</strong></td>
<td>ASTM F88/F88M</td>
<td>Standard test method for seal strength of flexible Barrier materials</td>
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<td>EN 868–5</td>
<td>Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods</td>
<td>NO</td>
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<td><strong>Specification development</strong></td>
<td>ASTM F2559/F2559F</td>
<td>Standard Guide for Writing a Specification for Sterilizable Peel Pouches</td>
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<td>ASTM F17</td>
<td>Standard Terminology Relating to Flexible Barrier Packaging</td>
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<td>ASTM F2097</td>
<td>Standard Guide for Design and Evaluation of Primary Flexible Packaging for Medical Products</td>
<td>NA</td>
<td>NA</td>
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<td><strong>Static electricity</strong></td>
<td>BS 6524</td>
<td>Method for determination of the surface resistivity of a textile fabric</td>
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<td>ASTM D257</td>
<td>Standard Test Methods for DC Resistance or Conductance of Insulating Materials</td>
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<tr>
<td>Sterile barrier system Integrity</td>
<td>ASTM F2228</td>
<td>Standard test method for non-destructive detection of leaks in medical packaging which incorporates porous barrier material by CO₂ tracer gas method</td>
<td>YES</td>
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<td>ASTM F3039</td>
<td>Standard Test Method for Detecting Leaks in Nonporous Packaging or Flexible Barrier Materials by Dye Penetration</td>
<td>YES</td>
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<td>ASTM F1929</td>
<td>Standard test method for detecting seal leaks in porous medical packaging by dye penetration</td>
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<td>ASTM F2227</td>
<td>Standard test method for non-destructive detection of leaks in non-sealed and empty medical packaging trays by CO₂ tracer gas method</td>
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<td>ASTM F2391</td>
<td>Standard Test Method for Measuring Package and Seal Integrity Using Helium as the Tracer Gas</td>
<td>YES</td>
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<td>ASTM F2096</td>
<td>Standard test method for detecting gross leaks in packaging by internal pressurization (Bubble test)</td>
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<td>ASTM F1886/F1886M</td>
<td>Standard test method for determining integrity of seals for medical packaging by visual inspection</td>
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<td>ASTM F2338</td>
<td>Standard test method for non-destructive detection of leaks in packages by vacuum decay</td>
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<td>ASTM D3078</td>
<td>Standard test method for determination of leaks in flexible packaging by bubble emission</td>
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<td>ASTM F2095</td>
<td>Standard test methods for pressure decay leak test for flexible packages with and without restraining plates</td>
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<td>ASTM F3004</td>
<td>Standard test method for evaluation of seal quality and integrity using airborne ultrasound</td>
<td>NO&lt;sup&gt;e&lt;/sup&gt;</td>
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<td>Sulfates</td>
<td>ISO 9198</td>
<td>Paper, board and pulps — Determination of water-soluble sulfates</td>
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<td>YES</td>
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<td>TAPPI T255</td>
<td>Water-soluble sulfates in pulp and paper, Test Method</td>
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<td>YES</td>
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<td>EN 868–4</td>
<td>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)</td>
<td>NO</td>
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<td>Tear resistance</td>
<td>ASTM D1424</td>
<td>Standard test method for tearing strength of fabrics by falling-pendulum (Elmendorf-type) apparatus</td>
<td>YES</td>
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<td>ASTM D1922</td>
<td>Standard test method for propagation tear resistance of plastic film and thin sheeting by pendulum method</td>
<td>YES</td>
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<td>ASTM D1938</td>
<td>Standard test method for tear-propagation resistance (trouser tear) of plastic film and thin sheeting by a single tear-method</td>
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<td>JIS P-8116</td>
<td>Paper — Determination of tearing resistance — Elmendorf tearing tester method</td>
<td>YES</td>
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<td>ISO 1974</td>
<td>Paper — Determination of tearing resistance (Elmendorf method)</td>
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<td>Tensile properties</td>
<td>ISO 1924-2</td>
<td>Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method</td>
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<td>(JIS P-8113)</td>
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<td>ISO 1924-3</td>
<td>Paper and board — Determination of tensile properties — Part 3: Constant rate of elongation method (100 mm/min)</td>
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<td>ASTM D882</td>
<td>Standard test method for tensile properties of thin plastic sheeting</td>
<td>YES</td>
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<td>ASTM D5034</td>
<td>Standard test method for breaking strength and elongation of textile fabrics (Grab test)</td>
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<td>TAPPI T494</td>
<td>Tensile properties of paper and paperboard (using constant rate of elongation apparatus)</td>
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<td><strong>Thickness/Density</strong></td>
<td>ISO 534</td>
<td>Paper and board — Determination of thickness, density and specific volume</td>
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<td>JIS P-8118</td>
<td>Paper and board — Determination of thickness, density and specific volume</td>
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<td>ASTM F2251</td>
<td>Standard test method for thickness measurement of flexible packaging materials</td>
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<td>TAPPI T551</td>
<td>Thickness of Paper and Paperboard (Soft Platen Method)</td>
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<td>TAPPI T411</td>
<td>Thickness (calliper) of paper, paperboard and combined board</td>
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<td><strong>Water resistance</strong></td>
<td>ISO 811</td>
<td>Textile fabrics — Determination of resistance to water penetration — Hydrostatic pressure test</td>
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<td>EDANA 170–1</td>
<td>Wet barrier — Mason Jar</td>
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<td>ISO 535</td>
<td>Paper and board — Determination of water absorptiveness — Cobb method</td>
<td>YES</td>
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<td>AATCC-127</td>
<td>Water resistance: Hydrostatic pressure test</td>
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<td>TAPPI T441</td>
<td>Water absorptiveness of sized (non-bibulous) paper, paperboard, and corrugated fiberboard (Cobb test)</td>
<td>YES</td>
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<td>EN 868–2</td>
<td>Packaging for terminally sterilized medical devices – Part 2: Sterilization wrap – Requirements and test methods (Annex C: Method for the water repellency)</td>
<td>NO</td>
<td>NO&lt;sup&gt;b&lt;/sup&gt;</td>
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<td><strong>Wet burst in wet condition</strong></td>
<td>ISO 3689</td>
<td>Paper and board — Determination of bursting strength after immersion in water</td>
<td>NO</td>
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<td>Wet tensile properties</td>
<td>ISO 3781</td>
<td>Paper and board — Determination of tensile strength after immersion in water</td>
<td>NO</td>
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<td>JIS P-8135</td>
<td>Paper and board — Determination of tensile strength after immersion in water</td>
<td>NO</td>
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<td>TAPPI T456</td>
<td>Tensile breaking strength of water-saturated paper and paperboard (&quot;wet tensile strength&quot;)</td>
<td>YES</td>
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</table>

a NA – not applicable  
d ASTM standard has only statement of precision.  
e Each material and/or package must have its own R&R study conducted.
Annex C
(normative)

Test method for defining impermeable materials to the passage of air

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

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

NOTE For the purpose of ISO 11607-1 and -2, 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 porosity may 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. Sterilisation 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, i.e. 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.

Environmental performance of products and their production processes including the disposal of all kinds of waste is generally controlled by national or regional law. For example, reduction of waste, by using less raw material for production of packaging for terminally sterilized medical devices has the potential to reduce environmental impact. The use of life-cycle thinking applied to a product when making packaging system design decisions can have significantly more impact. “Life-cycle thinking” means consideration for all environmental aspects of a product at all stages of its lifecycle.

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 being, as long as it is used as intended.

The following is 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.

— ISO 14001:2015 Environmental management systems -- Requirements with guidance for use
— ISO 14006:2011 Environmental management systems -- Guidelines for incorporating ecodesign
— ISO 14020:2000 Environmental labels and declarations -- General principles
— ISO 14021:2016 Environmental labels and declarations -- Self-declared environmental claims (Type II environmental labelling)
— ISO 14024:1999 Environmental labels and declarations -- Type I environmental labelling -- Principles and procedures
— ISO 14025:2006 Environmental labels and declarations -- Type III environmental declarations -- Principles and procedures
— ISO/TR 14062:2002 Environmental management -- Integrating environmental aspects into product design and development
— ISO 14040:2006 Environmental management -- Life cycle assessment -- Principles and framework
— ISO 14044:2006 Environmental management -- Life cycle assessment -- Requirements and guidelines
— ISO 50001:2011 Energy management systems -- Requirements with guidance for use
— AAMI TIR 65: 2015 Sustainability of medical devices—Elements of a responsible product life cycle
— ISO 18601:2013 Packaging and the environment -- General requirements for the use of ISO standards in the field of packaging and the environment
— ISO 18602:2013 Packaging and the environment -- Optimization of the packaging system
— ISO 18603:2013 Packaging and the environment – Reuse
— ISO 18604:2013 Packaging and the environment -- Material recycling
— ISO 18605:2013 Packaging and the environment -- Energy recovery
— ISO 18606:2013 Packaging and the environment -- Organic recycling
— EN 13427:2004 Packaging - Requirements for the use of European Standards in the field of packaging and packaging waste
— EN 13428:2004 Packaging - Requirements specific to manufacturing and composition - Prevention by source reduction
— EN 13429:2004 Packaging – Reuse
— EN 13430:2004 Packaging - Requirements for packaging recoverable by material recycling
— EN 13431:2004 Packaging - Requirements for packaging recoverable in the form of energy recovery, including specification of minimum inferior calorific value
— EN 13432:2000/AC:2005 Packaging - Requirements for packaging recoverable through composting and biodegradation - Test scheme and evaluation criteria for the final acceptance of packaging
Annex E
(informative)


The European Commission has published the new medical device regulations on the 5th of May 2017. The European Commission has not issued a standardization request to CEN for the new EU Regulation as of the DIS (enquiry) stage of this document. This annex is a draft of the Annex ZA that will be completed and submitted when the details of the standardization request are available.

This standard is designed to be used as one voluntary means of conforming to specific aspects of the general safety and performance requirements (SPRs) of Regulation (EU) 2017/745 as detailed in the table below.
### Table E.1 — Correspondence between this standard and Annex I of Regulation (EU) 2017/745

<table>
<thead>
<tr>
<th>Safety and performance requirements (SPRs) of Regulation (EU) 2017/745</th>
<th>Clause(s)/sub-clause(s) of this standard</th>
<th>Remarks/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>11.1 Devices and their manufacturing processes shall be designed in such a way as to eliminate or to reduce as far as possible the risk of infection to patients, users and, where applicable, other persons. The design shall: (a) reduce as far as possible and appropriate the risks from unintended cuts and pricks, such as needle stick injuries, (b) allow easy and safe handling, (c) reduce as far as possible any microbial leakage from the device and/or microbial exposure during use, and (d) prevent microbial contamination of the device or its content such as specimens or fluids.</td>
<td>6.1, 6.1.1, 6.1.2, 6.1.5</td>
<td>SPR 11.1 (b) and (d) are covered only in respect of the function of the sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use, and to allow for aseptic presentation but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes). The standard includes a way to evaluate the packaging design in terms of usability to provide supportive evidence for 11.1 (b) covering the aspect of aseptic presentation. The standard includes a packaging performance and stability testing approach as supportive evidence for 11.1 (d).</td>
</tr>
<tr>
<td>11.4 Devices delivered in a sterile state shall be designed, manufactured and packaged in accordance with appropriate procedures, to ensure that they are sterile when placed on the market and that, unless the packaging which is intended to maintain their sterile condition is damaged, they remain sterile, under the transport and storage conditions specified by the manufacturer, until that packaging is opened at the point of use. It shall be ensured that the integrity of that packaging is clearly evident to the final user.</td>
<td>4.4, 5.2, 6.1.1, 6.1.2, 6.1.5, 6.1.7, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>SPR 11.4 is covered only in respect of the function of sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes). In this respect damage to the &quot;packaging which is intended to maintain their sterile condition&quot; is taken to mean damage to or loss of integrity of the sterile barrier system only. Regarding the aspects of &quot;clearly evident integrity of the packaging&quot;, this Draft International Standard does not include criteria.</td>
</tr>
<tr>
<td>11.5 Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.</td>
<td>4.4, 5.3.1, 5.3.2, 5.3.3, 6.1.1, 6.1.2, 6.1.5, 6.1.7, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>SPR 11.5 is covered only in respect of the compatibility between the packaging and the selected sterilisation processes including packaging system performance testing and sterile barrier system stability testing, but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes).</td>
</tr>
</tbody>
</table>

Note 1 The text in blue will be removed from the final annex Z if the template is similar than for the MDD.

Note 2 Date of revision needs to be replaced by the final date when the standard is published.
WARNING — Presumption of conformity is valid only after publication of an annex in the European version of this standard based on the standardization request and guidance of the European Commission and after the reference to the EU standard is published in the respective list in the Official Journal of the European Union.

The European Commission has published the new in vitro diagnostic regulations on the 5th of May 2017. The European Commission has not issued a standardization request to CEN for the new EU Regulation as of the DIS (enquiry) stage of this document. This annex is a draft of the Annex ZA that will be completed and submitted when the details of the standardization request are available.

This standard is designed to be used as one voluntary means of conforming to specific aspects of the general safety and performance requirements (SPRs) of Regulation (EU) 2017/746 as detailed in the table below.

<table>
<thead>
<tr>
<th>Safety and performance Requirements (SPRs) of Regulation (EU) 2017/746</th>
<th>Clause(s)/sub-clause(s) of this standard</th>
<th>Remarks/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>11.2</strong> Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that their sterile condition or microbial state is maintained under the transport and storage conditions specified by the manufacturer until that packaging is opened at the point of use, unless the packaging which maintains their sterile condition or microbial state is damaged.</td>
<td>4.4, 5.2, 6.1.1, 6.1.2, 6.1.5, 6.1.7, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>SPR 11.2 is covered only in respect of the function of sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes). In this respect damage to the “packaging which maintains their sterile condition” is taken to mean damage to or loss of integrity of the sterile barrier system only.</td>
</tr>
<tr>
<td><strong>11.3</strong> Devices labelled as sterile shall be processed, manufactured, packaged and, sterilised by means of appropriate, validated methods.</td>
<td>4.4, 5.3.1, 5.3.3, 5.3.2, 6.1.2, 6.1.5, 6.1.7, 6.1.1, 8.1, 8.2.2, 8.2.1, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>SPR 11.3 is covered only in respect of the compatibility between the packaging and the selected sterilisation processes including packaging system performance testing and sterile barrier system stability testing, but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes).</td>
</tr>
</tbody>
</table>

Note 1 The text in blue will be removed from the final annex Z if the template is similar than for the MDD.

Note 2 Date of revision needs to be replaced by the final date when the standard is published.
WARNING — Presumption of conformity is valid only after publication of an annex in the European version of this standard based on the standardization request and guidance of the European Commission and after the reference to the EU standard is published in the respective list in the Official Journal of the European Union.
Annex ZA
(informative)

Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/023 concerning the development of European standards relating to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.
Table ZA.1 — Correspondence between this European Standard and Annex I of Directive 93/42/EEC [OJ L 169]

<table>
<thead>
<tr>
<th>Essential Requirements of Directive 93/42/EEC</th>
<th>Clause(s)/sub-clause(s) of this EN</th>
<th>Remarks/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.1</td>
<td>6.1, 6.1.1, 6.1.2, 6.1.5, 7</td>
<td>E.R. 8.1 is covered only in respect of the function of the sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes). The standard includes a way to evaluate the packaging design in terms of usability to provide supportive evidence for the aspect of aseptic presentation.</td>
</tr>
<tr>
<td>8.3</td>
<td>4.4, 5.2, 6.1.2, 6.1.5, 6.1.7 6.1.1, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>E.R. 8.3 is covered only in respect of the function of sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes). In this respect damage to the “protective packaging” is taken to mean damage to or loss of integrity of the sterile barrier system only.</td>
</tr>
<tr>
<td>8.4</td>
<td>4.4, 5.3.1, 5.3.3, 5.3.2, 6.1.1, 6.1.2, 6.1.5, 6.1.7 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>E.R. 8.4 is covered only in respect of the compatibility between the packaging and the selected sterilisation processes including packaging system performance testing and sterile barrier system stability testing, but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes).</td>
</tr>
</tbody>
</table>

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.
Annex ZB
(informative)

Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered

This European Standard has been prepared under a Commission's standardization request M/432 to provide one voluntary means of conforming to essential requirements of Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [OJ L 189].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 90/385/EEC as amended by 2007/47/EC. This means that risks have to be reduced ‘as far as possible’, ‘to a minimum’, ‘to the lowest possible level’, ‘minimized’ or ‘removed’, according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer’s policy for determining acceptable risk must be in compliance with Essential Requirements 1, 4, 5, 8, 9 and 10 of the Directive.

NOTE 3 This Annex ZB is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

Table ZB.1 — Correspondence between this European Standard and Annex I of Directive 90/385/EEC [OJ L 189]

<table>
<thead>
<tr>
<th>Essential Requirements of Directive 90/385/EEC</th>
<th>Clause(s)/sub-clause(s) of this EN</th>
<th>Remarks/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>7</td>
<td>6.1.1, 6.1.5, 6.1.7, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6, 7</td>
<td>E.R. 7 is covered only in respect of the function of sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes).</td>
</tr>
</tbody>
</table>

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other Union legislation may be applicable to the products falling within the scope of this standard.
Annex ZC
(informative)

Relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered


Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of this standard given in Table ZC.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 98/79/EC. This means that risks have to be reduced ‘as far as possible’, ‘to a minimum’, ‘to the lowest possible level’, ‘minimized’ or ‘removed’, according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer’s policy for determining acceptable risk must be in compliance with Essential Requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 This Annex ZC is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 When an Essential Requirement does not appear in Table ZC.1, it means that it is not addressed by this European Standard.
### Table ZC.1 — Correspondence between this European Standard and Annex I of Directive 98/79/EC [OJ L 331]

<table>
<thead>
<tr>
<th>Essential Requirements of Directive 98/79/EC</th>
<th>Clause(s)/sub-clause(s) of this EN</th>
<th>Remarks/Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>B2.3</td>
<td>4.4, 5.2, 6.1.1, 6.1.2, 6.1.5, 6.1.7, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>E.R. B2.3 is covered only in respect of the function of sterile barrier system(s) to protect the sterility of the device from the point of sterilisation to the point of use and to allow for aseptic presentation but only if the requirements EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes). In this respect damage to the “protective packaging” is taken to mean damage to or loss of integrity of the sterile barrier system only.</td>
</tr>
<tr>
<td>B2.4</td>
<td>4.4, 5.3.1, 5.3.2, 5.3.3, 6.1.1, 6.1.2, 6.1.5, 6.1.7, 8.1, 8.2.1, 8.2.2, 8.3.1, 8.3.2, 8.3.3, 8.3.4, 8.3.5, 8.3.6</td>
<td>E.R. B2.4 is covered only in respect of the compatibility between the packaging and the selected sterilisation processes including packaging system performance testing and sterile barrier system stability testing, but only if the requirements of EN ISO 11607-2:[date of revision] are met as well (validation requirements for forming, sealing and assembling processes).</td>
</tr>
</tbody>
</table>

**WARNING 1** — Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

**WARNING 2** — Other Union legislation may be applicable to the products falling within the scope of this standard.
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