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Packaging for terminally sterilized medical devices —

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

Emballages des dispositifs médicaux stérilisés au stade terminal —

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

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Foreword

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Introduction

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

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

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

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

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

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

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

Packaging for terminally sterilized medical devices —

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

1 Scope

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

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

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

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

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

2 Normative references

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

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

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

3 Terms and definitions

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

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

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

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

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

[SOURCE: ISO 11139:2018, 3.13]

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

[SOURCE: ISO 11139:2018, 3.23]

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

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

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

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

[SOURCE: ISO 11139:2018, 3.52]

3.5
control
regulation of variables within specified limits

[SOURCE: ISO 11139:2018, 3.63]

3.6
expiry date
date by which product should be used

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

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

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

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

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

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

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

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

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

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

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

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

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

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

— disinfection substances;

— aids for persons with disabilities;

— devices incorporating animal and/or human tissues;

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

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

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

[SOURCE: ISO 11139:2018, 3.169]

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

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

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

[SOURCE: ISO 11139:2018, 3.192]

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

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

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

3.13
product
tangible result of a process

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

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

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

3.14
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use

[SOURCE: ISO 11139:2018, 3.219]

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

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

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

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

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

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

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

[SOURCE: ISO 11139:2018, 3.235]

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

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

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

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

[SOURCE: ISO 11139:2018, 3.245]

3.20
seal strength
mechanical capacity of the seal to withstand force

[SOURCE: ISO 11139:2018, 3.246]

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

[SOURCE: ISO 11139:2018, 3.251]

3.22
sterile
free from viable microorganisms

[SOURCE: ISO 11139:2018, 3.271]

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

[SOURCE: ISO 11139:2018, 3.272]

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

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

[SOURCE: ISO 11139:2018, 3.273]

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

[SOURCE: ISO 11139:2018, 3.278]

3.26
sterilizing agent

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

[SOURCE: ISO 11139:2018, 3.288]

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

[SOURCE: ISO 11139:2018, 3.295]

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

[SOURCE: ISO 11139:2018, 3.296]

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

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

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

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

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

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

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

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

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

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

4 General requirements

4.1 Quality systems

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

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

4.2 Risk management

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

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

4.3 Sampling

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

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

4.4 Test methods

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

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

NOTE Pass/fail is a type of acceptance criterion.

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

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

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

— determination of test method repeatability;

— determination of test method reproducibility;

— establishment of test method sensitivity for integrity tests.

4.5 Documentation

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

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

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

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

5 Materials, preformed sterile barrier systems and sterile barrier systems

5.1 General requirements

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

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

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

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

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

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

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

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

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

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

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

a) temperature range;

b) pressure range;

c) humidity range;

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

e) exposure to sunlight or UV light;

f) cleanliness;

g) bioburden;

h) electrostatic properties.

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

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

5.1.6 The following properties shall be evaluated:

a) microbial barrier (see 5.2);

b) biocompatibility and toxicological attributes;

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

c) physical and chemical properties;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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