TECHNICAL SPECIFICATION

ISO/TS 16775

First edition
2014-05-15

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

Emballages des dispositifs médicaux stérilisés au stade terminal — Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2

Reference number
ISO/TS 16775:2014(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. 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. 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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

Introduction

Sterile barrier systems need to ensure the sterility of their contents until opened for use and ensure aseptic presentation.

The sterile barrier system, depending on conditions of handling, distribution or storage, may provide adequate protection for the sterile medical device. In circumstances where the packaged and sterilized device undergoes repeated handling, additional protective packaging may need to be combined with the sterile barrier system to create a packaging system.

Each establishment should evaluate the performance of each sterile barrier system or packaging system before selection and implementation to ensure conditions for sterilization, storage, and handling can be met. Each establishment that manages sterile items should have a documented plan of education on how to store, handle and transport sterile items.

Regional differences in quality management systems and other requirements exist and these might involve different approaches to human resource management. In any case however a sound education process is a key element and facilities should ensure that its personnel are aware of the relevance and importance of their packaging and sterilization activities for the safety of the patient.

ISO 11607-1 specifies the requirements for materials, sterile barrier systems, and packaging systems, including the qualification of the packaging system design and evaluation of that design, ISO 11607-2 specifies the requirements for packaging process validation. Both of these documents provide standards to ensure medical device protection, the ability to sterilize, maintenance of sterile package integrity and aseptic presentation. The scope of each of these standards applies to health care facilities and wherever medical devices are packaged and sterilized. It is recognized that the circumstances of the application of these standards will be different when they are used in a health care facility from when they are used by a medical device manufacturer or reprocessor.

The conditions of use of this guidance may vary widely around the world. ISO 11607-1 and ISO 11607-2 and this guidance document provide a guideline for use, subject to interpretation by circumstance and regulatory environments. In some regions of the world health care facility compliance to the series ISO 11607 is a national or regional regulatory requirement, in some regions the series ISO 11607 is considered guidance for health care facilities. For instance, it is recognized that in certain regions or regulatory applications conformance to ISO 11607-1 may be demonstrated but not conformance to ISO 11607-2, which requires process validation by the user. In other regions, where compliance to both ISO 11607-1 and ISO 11607-2 is a national regulatory requirement, this document will also provide guidance on performing validation. Clause 3 of this guidance document is applicable to health care facilities and Clause 4 is applicable to industry. Further guidance is given in Annexes A to S that may be applicable to health care facilities and/or industry, as indicated.

In Europe ISO 11607-1 assists the conformity assessment procedure for manufacturers and is designed and used as a tool for demonstrating compliance with the relevant essential requirements of the Medical Device Directive. Compliance with the standard is always voluntary.

At the time of publication of this document, Amendments to ISO 11607-1 and ISO 11607-2 are in the ballot process. This guidance document already considers the revised versions with the understanding that specific references to numbering may have changed. Annex B of ISO 11607-1 on test methods has been extensively revised and should be considered when available.

Packaging for terminally sterilized medical devices — Guidance on the application of ISO 11607-1 and ISO 11607-2

1 Scope

This Technical Specification provides guidance for the application of the requirements contained in ISO 11607-1 and ISO 11607-2. It does not add to, or otherwise change, the requirements of ISO 11607-1 and/or ISO 11607-2. This is an informative document, not normative. It does not include requirements to be used as basis of regulatory inspection or certification assessment activities.

The guidance can be used to better understand the requirements of ISO 11607-1 and/or ISO 11607-2 and illustrates some of the variety of methods and approaches available for meeting the requirements of those International Standards. It is not required that this document be used to demonstrate compliance with them.

Guidelines are given for evaluation, selection and use of packaging materials, preformed sterile barrier systems, sterile barrier systems and packaging systems. Guidance on validation requirements for forming, sealing and assembly processes is also given.

This Technical Specification provides information for health care facilities (see Clause 3) and for the medical devices industry (see Clause 4).

It does not provide guidance for applications of packaging materials and systems after their opening. In the use of packaging for other purposes such as a “sterile field” or transport of contaminated items, other regulatory standards will apply.

2 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11607-1 and ISO 11607-2 and the following apply.

2.1
packaging system
combination of the sterile barrier system and protective packaging

[SOURCE: ISO/TS 11139:2006, 2.28]

Note 1 to entry: The packaging system includes the sterile barrier system and the protective packaging. However, if the sterile barrier system protects the medical device, facilitates aseptic presentation, and is resilient enough not to require additional protective packaging, the sterile barrier system would also fulfil the requirements of a packaging system. Protective packaging is not always necessary however aseptic opening/presentation has to be ensured in all cases.

2.2
protective packaging
configuration of materials designed to prevent damage to the sterile barrier system and its contents assembly until the point of use

[SOURCE: ISO/TS 11139:2006, 2.37]

Note 1 to entry: National or regional regulations may require that protective packaging is used to avoid the potential contamination of the surgical environment. These regulations may also require that the protective packaging is removed prior to introduction of the sterile barrier system into the surgical environment.

Note 2 to entry: Protective packaging protects the sterile barrier and the contents. Examples would include a dust cover, a box, transport tray.

2.3
sterile barrier system
SBS
minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use

[SOURCE: ISO/TS 11139:2006, 2.44]

2.4
preformed sterile barrier system
sterile barrier system that is supplied partially assembled for filling and final closure or sealing

EXAMPLE Pouches, bags, and open reusable container.

[SOURCE: ISO/TS 11139:2006, 2.31]

Note 1 to entry: Preformed sterile barrier systems exist in a wide range of forms. The examples listed above are not intended to be all inclusive.

3 Guidance for health care facilities

IMPORTANT — Written instructions for use should be obtained from the packaging material and/or medical device manufacturer concerning their recommendations for sterilization and the subsequent maintenance of sterility of a sterile barrier system.

3.1 Test methods

For guidance on the requirements for test methods contained in ISO 11607-1 and ISO 11607-2, see the health care annexes of this document.

3.2 Guidance for conformance to ISO 11607-1

3.2.1 General guidance for materials, preformed sterile barrier systems and sterile barrier systems

3.2.1.1 Preformed sterile barrier systems should be evaluated before purchase and use. Therefore, the supplier should consider providing a statement of compliance to the applicable sections of ISO 11607-1 for the materials and/or preformed sterile barrier systems to be purchased. Before introducing associated components (e. g. labels, tapes, tray liners) into production, users should confirm that they will be suitable for use in their specific applications and conditions of use.

3.2.1.2 The key concepts that apply to all packaging materials and components are as follows:

a) they should be made of known and traceable materials with processes capable of meeting the requirements of ISO 11607-1 (see requirements in ISO 11607-1:2006, 5.1.3, 5.1.4 and 5.1.5);

b) they should be non-toxic, for guidance see A.3.3 (see requirement in ISO 11607-1:2006, 5.1.6);

NOTE 1 If the sterile barrier system or associated components contain natural rubber latex, the sterile barrier system should be labelled indicating natural rubber latex is present.

c) there should be documented evidence that the ingress of microorganisms can be prevented when demonstrated under test conditions which consider sterilization process, handling, distribution, transport and storage (see requirement in ISO 11607-1:2006, 5.1.6 and 5.2);

d) they should have a demonstrated ability to meet the required physical properties for materials and closures (such as weight or grade, seal width and seal strength), resist tearing or puncture, be capable of opening or peeling in a continuous and homogenous manner, without delamination tearing (see requirements in ISO 11607-1:2006, 5.1.7 and 5.1.9);

e) they should be compatible with the intended sterilization process and parameters capable of producing a sterile medical device (see requirement in ISO 11607-1:2006, 5.3);

f) they should be compatible with the labelling system; if present, have colour fast printing inks that do not degrade, fade or become illegible after exposure to the intended sterilization process (see requirement in ISO 11607-1:2006, 5.4);

g) they should be protected from the effects of environmental conditions (e.g. relative humidity, direct sunlight or fluorescent light, temperature) during storage (see requirement in ISO 11607-1:2006, 5.5 and Clause 7);

NOTE 2 Suggested storage conditions and shelf life should be provided by the material or preformed sterile barrier system manufacturer. If anticipated or actual storage is outside these conditions the manufacturer should be consulted.

h) they should allow aseptic presentation.

NOTE 3 Instructions for aseptic presentation should be provided by the manufacturer of the medical device and/or packaging system.

NOTE 4 The internet is a useful tool for finding information on materials, see Annex N.

3.2.2 Design and development guidance for packaging systems (ISO 11607-1:2006, 6.1 and 6.2)

3.2.2.1 Selection criteria

When a health care facility determines which packaging system to use, the design and development guidance for those packaging systems should be considered (see requirements in ISO 11607-1:2006, 6.1 and 6.2). When a health care facility uses a contract packager or sterilizer additional considerations are necessary (see Annex P).

The materials and systems chosen should:

a) be intended for use in medical packaging applications, as stated by the manufacturer;

b) be supported by technical information from the manufacturer confirming that it meets the requirements of ISO 11607-1 that relate to materials;

c) provide adequate protection for the medical device(s) during specified intended storage and transportation conditions to the point of use;

d) allow for and be compatible with the intended sterilization process, and have the ability to withstand conditions of the chosen process;

NOTE Not all materials are appropriate for all sterilization processes. Information on compatibility with a given sterilization process is typically provided by the manufacturer of the medical device and/or packaging system. For further explanation of challenges of common sterilization processes see Annex B.

e) maintain sterile barrier integrity until its time of use;

f) ensure aseptic presentation at the point of use;

g) allow a method of closure that is tamper evident;

h) allow for ease of identification of contents.

The user of the packaging materials should ensure that the sterile barrier system or packaging system complies with ISO 11607-1, that requirements concerning product compatibility are met and that processes for packaging, sterilization, storage and distribution are validated and controlled.

3.2.2.2 Selection considerations

The selection process at the health care facility should include an evaluation of the ability of both the sterile barrier system and protective packaging (if required) utilized to maintain the integrity of that sterile barrier system until its time of use and permit aseptic presentation at the point of use.

The choice of packaging components will be dependent on the risk associated with the medical device, its conditions of use, the storage and transport requirements and health care procedures practiced at the facility. These risks should be analysed by the health care facility and procedures put in place to mitigate/control those risks (see Annex K).

To choose the most appropriate material for the sterile barrier system and/or packaging system, the following should be considered:

a) Duration and conditions of storage may affect the type of sterile barrier system or packaging system needed. Some items may be stored for some time before use and may require a more durable sterile barrier system and/or the addition of protective packaging. The more the sterile barrier system or packaging system is handled the greater the probability that cracks, lid deformation, gasket damage, tears, holes or material separation may occur.

b) Size, weight and shape of the item to be sterilized should be considered. Some items will require more durable or more flexible sterile barrier systems than others.

c) If multiple types of packaging components are to be used it is important to verify that components are compatible with each other as well as the product contained inside and the intended sterilization process.

d) The means and conditions of transport should be considered. While in some cases routes are exclusively inside the facility, they can also be between different facilities. Exposure of the packaging systems to the uncontrolled environment may significantly increase the risk of loss of integrity of the package, compromise aseptic opening or contaminate the contents.

3.2.2.3 Assembly considerations

The following aspects should be considered:

a) Medical devices should be oriented to facilitate aseptic presentation.

b) Sharp items should be shielded so that the user is protected from injury and the sterile barrier system and medical device is protected from damage.

c) Associated components can be used inside the sterile barrier system in order to ease or facilitate the organization, drying or aseptic presentation (e. g. inner wrap, instrument organizer tray, tray liners or a containment device around the medical device).

d) The protection devices or associated components should:

   1) be non-toxic, be intended for use in medical packaging applications, as stated by the manufacturer;

   2) provide protection of the medical device(s) during storage and transportation to the point of use;

   3) allow for and be compatible with the intended sterilization process, and have the ability to withstand conditions of chosen process;

NOTE 1 Not all materials are appropriate for all sterilization processes. Information on compatibility with a given sterilization process is typically provided by the manufacturer. For further explanation of challenges of common sterilization processes see Annex B.

4) not undergo chemical or physical change to such an extent that the performance or safety is impaired or the medical device that they contact is adversely affected;

5) not compromise aseptic presentation;

6) allow for easy identification of contents;

7) be stored in a controlled environment to maintain cleanliness and fitness for use.

e) The weight of the packaging system and its contents should not exceed national regulations for manual handling.

NOTE 2 Current national regulations range from about 5 kg to 11,4 kg.

3.2.2.4 Labelling considerations

Part of the selection process should include consideration of how labelling is to be accomplished. The facility's labelling procedure for the sterile barrier system or packaging system should include the following:

a) When identification is performed in a health care facility:

— for pouches and reels the label should be placed on the film if applied before sterilization or on either side if after, the label should not conceal the device;

— for pouches and reels printing or writing should be placed outside the area enclosed by the outside dimensions of the seals;

— care should be taken when applying labels to filled sterile barrier systems so as not to damage packaging materials or contents.

b) Writing on wrapped packages should be on the closure tape, not directly on wrappers.

c) Special labels intended for a specific sterilization process may be written on. If these labels are used they should not impede the sterilization process (i.e. should not block the breathable area of the package).

d) Labelling should remain securely adhered to the sterile barrier system through the sterilization process and storage until the point of use.

e) Labels or closure tapes used as labels, and their adhesive systems should be non-toxic.

f) Only non-toxic ink that is suitable for use with the chosen sterilization process should be used.

g) Ballpoint pens or any writing instrument with the potential for creating a hole or puncture in the sterile barrier system should not be used.

3.2.2.5 Regulatory considerations

Specific national or regional regulatory requirements may apply. These requirements should be considered during the selection process for a sterile barrier system and/or for a packaging system.