



SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 16775:2014
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Embalaza za končno sterilizirane medicinske pripomočke - Smernice za uporabo ISO 11607-1 in ISO 11607-2 (ISO/TS 16775:2014)

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

Verpackungen für in der Endverpackung sterilisierte Medizinprodukte - Teil 3: Leitfaden für die Anwendung von ISO 11607-1 und ISO 11607-2 (ISO/TS 16775:2014)

Emballages des dispositifs médicaux stérilisés au stade terminal - Lignes directrices relatives à l'application de l'ISO 11607-1 et l'ISO 11607-2 (ISO/TS 16775:2014)

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**Packaging for terminally sterilized medical devices - Guidance
on the application of ISO 11607-1 and ISO 11607-2 (ISO
16775:2014)**

Emballages des dispositifs médicaux stérilisés au stade
terminal - Lignes directrices relatives à l'application de l'ISO
11607-1 et l'ISO 11607-2 (ISO 16775:2014)

Verpackungen für in der Endanwendung sterilisierte
Medizinprodukte - Leitfaden für die Anwendung von ISO
11607-1 und ISO 11607-2 (ISO 16775:2014)

This Technical Specification (CEN/TS) was approved by CEN on 18 February 2014 for provisional application.

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Foreword

This document (CEN ISO/TS 16775:2014) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers for medical purposes" the secretariat of which is held by DIN.

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Endorsement notice

The text of ISO/TS 16775:2014 has been approved by CEN as CEN ISO/TS 16775:2014 without any modification.

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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
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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. 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*.

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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.

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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.

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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](#).

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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.