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Nadomešča:

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Embalaža za končno sterilizirane medicinske pripomočke - 1. del: Zahteve za materiale, sterilne pregradne sisteme in sisteme embalaže (ISO 11607-1:2019)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarriersysteme und Verpackungssysteme (ISO 11607-1:2019)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage (ISO 11607-1:2019)

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ICS:

11.080.30 Sterilizirana embalaža Sterilized packaging

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Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière stérile et aux systèmes d'emballage (ISO 11607-1:2019)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO 11607-1:2019)

This European Standard was approved by CEN on 3 November 2018.

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CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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COMITÉ EUROPÉEN DE NORMALISATION
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European foreword

This document (EN ISO 11607-1:2020) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 "Sterilizers and associated equipment for processing of medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11607-1:2017.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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STANDARD

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2019-02

**Packaging for terminally sterilized
medical devices —**

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

iTeh STANDARD PREVIEW
*Emballages des dispositifs médicaux stérilisés au stade terminal —
Partie 1: Exigences relatives aux matériaux, aux systèmes de barrière
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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 method(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.

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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.

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2 Normative references

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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]

ISO 11607-1:2019(E)**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 **(standards.iteh.ai)**

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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.]