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Embalaža za končno sterilizirane medicinske pripomočke - 1. del: Zahteve za materiale, sterilne pregradne sisteme in sisteme embalaže (ISO/DIS 11607-1:2017)

Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO/DIS 11607-1:2017)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 1: Anforderungen an Materialien, Sterilbarrieresysteme und Verpackungssysteme (ISO/DIS 11607-1:2017)

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/DIS 11607-1:2017)

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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

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 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 will supersede EN ISO 11607-1:2009+A1:2014.

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 — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 5636-5		ISO 5636-5:2013

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 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 pre-formed 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

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

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.