SLOVENSKI STANDARD
oSIST prEN ISO 11607-2:2018

01-januar-2018

Embalaža za končno sterilizirane medicinske pripomočke - 2. del: Zahteve za validacijo pri procesih oblikovanja, označevanja in sestavljanja (ISO/DIS 11607-2:2017)

Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO/DIS 11607-2)

Verpackungen für in der Endverpackung zu sterilisierende Medizinprodukte - Teil 2: Validierungsanforderungen an Prozesse der Formgebung, Siegelung und des Zusammenstellens (ISO/DIS 11607-2:2017)

Emballages des dispositifs médicaux stérilisés au stade terminal - Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage (ISO/DIS 11607-2:2017)

Ta slovenski standard je istoveten z: **prEN ISO 11607-2**

ICS:

11.080.30	Sterilizirana embalaža	Sterilized packaging

oSIST prEN ISO 11607-2:2018 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 11607-2

ISO/TC **198**

Secretariat: **ANSI**

Voting begins on:
2017-09-18

Voting terminates on:
2017-12-11

Packaging for terminally sterilized medical devices —

Part 2:
Validation requirements for forming, sealing and assembly processes

Emballages des dispositifs médicaux stérilisés au stade terminal —

Partie 2: Exigences de validation pour les procédés de formage, scellage et assemblage

ICS: 11.080.30

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 11607-2:2017(E)

ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

Contents

Page

Foreword ..... **iv**

Introduction ..... **v**

1 Scope **1**

2 Normative references **1**

3 Terms and definitions **1**

4 General requirements **4**
4.1 General 4
4.2 Quality systems 4
4.3 Sampling 4
4.4 Test methods 4
4.5 Documentation 5

5 Validation of packaging processing **5**
5.1 General 5
5.2 Installation qualification (IQ) 6
5.3 Operational qualification (OQ) 7
5.4 Performance qualification (PQ) 7
5.5 Formal approval of the process validation 8
5.6 Process control and monitoring 8
5.7 Process changes and revalidation 8

6 Packaging system assembly **9**

7 Use of reusable sterile barrier systems **9**

8 Sterile fluid-path packaging **9**

Annex A (informative) **Process development** **10**

Annex B (informative) **Draft guidance on the relationship between this standard and the general safety and performance requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC** **11**

Annex C (informative) **Draft guidance on the relationship between this standard and general safety and performance requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU** **14**

Annex ZA (informative) **Relationship between this European Standard and the essential requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered** **16**

Annex ZB (informative) **Relationship between this European Standard and the essential requirements of Directive 90/385/EEC [OJ L 189] aimed to be covered** **18**

Annex ZC (informative) **Relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] aimed to be covered** **19**

Bibliography **21**

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), which has been technically revised.

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

— New definitions for process variable, process parameter and monitoring of processes.

— Alignments of various definitions with ISO 11139 to ensure harmonization throughout the standards under ISO/TC 198.

— The terminology of "critical" process parameters is discontinued and the concept of a process specification is introduced to include all elements required to manufacture a product that consistently meets specifications.

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

Introduction

Packaging for medical devices which shall be terminally sterilized should be designed and manufactured to ensure that the medical device can be sterilized and remain sterile under documented storage and transport conditions until the sterile barrier system is damaged or opened.

One of the most critical characteristics of a sterile barrier system and packaging system for sterile medical devices is the assurance of sterility maintenance. Medical devices delivered in a sterile state should have been manufactured, packed and sterilized by appropriate, validated methods. The development and validation of packaging processes are crucial to ensure that sterile barrier system integrity is attained and will remain so until opened by the users of sterile medical devices.

There should be a documented process validation program demonstrating the efficacy and reproducibility of all packaging and sterilization processes. Along with the sterilization process, some of the packaging operations that can affect sterile barrier system integrity are sealing, capping or other closure systems, cutting, form/fill/seal, assembly processes and subsequent handling. This part of ISO 11607 provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. 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.

The term “sterile barrier system” was introduced 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.

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 regulated as medical devices in many parts of the world.

Packaging for terminally sterilized medical devices —

Part 2:
Validation requirements for forming, sealing and assembly processes

1 Scope

This part of ISO 11607 specifies the requirements for development and validation of processes for packaging medical devices that are terminally sterilized. These processes include forming, sealing, and assembly of preformed sterile barrier systems, sterile barrier systems and packaging systems.

This part of ISO 11607 is applicable to industry, to health care facilities, and wherever medical devices are packaged and sterilized.

This part of ISO 11607 does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements may also be necessary for drug/device combinations.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

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
control
regulation of variables within specified limits

[SOURCE: ISO/DIS 11139:2017]

3.2
expiry date
indication of the date by which the product should be used

3.3
installation qualification
IQ
Process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation adhere to the approved specification

[SOURCE: ISO/DIS 11139:2017]

3.4
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]

3.5
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]

3.6
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: ISO/DIS 11139:2017]

3.7
packaging system
combination of the sterile barrier system and protective packaging

[SOURCE: ISO/DIS 11139:2017]

3.8
process parameter
specified value for a process variable

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

3.9
performance qualification
PQ
process of establishing by objective evidence that the process, under anticipated conditions, consistently produces a product which meets all predetermined requirements

[SOURCE: ISO/DIS 11139:2017]

3.10
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 containers

[SOURCE: ISO/DIS 11139:2017]

3.11
process parameter
specified value for a process variable

Note 1 to entry: The specification for a process includes the process parameters and their tolerances.

[SOURCE: ISO/DIS 11139:2017]

3.12
process variable
chemical or physical properties attribute within a cleaning, disinfection, packaging, or sterilization process, changes in which can alter its effectiveness

EXAMPLE Time, temperature, pressure, concentration, humidity, wavelength

[SOURCE: ISO/DIS 11139:2017]

3.13
product
tangible result of a process

EXAMPLE Raw material(s), intermediate(s), sub-assembly(ies), healthcare product(s)

Note 1 to entry: For the purposes 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]

3.14
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

3.15
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]

3.16
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]

3.17
reusable container
rigid sterile barrier system designed to be repeatedly used

3.18
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

3.19
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.