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Packaging for terminally sterilized medical devices -
Part 2: Validation requirements for forming, sealing and
assembly processes (ISO 11607-2:2019)

EESTI STANDARDI EESSÕNA

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See Eesti standard EVS-EN ISO 11607-2:2020 sisaldab Euroopa standardi EN ISO 11607-2:2020 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11607-2:2020 consists of the English text of the European standard EN ISO 11607-2:2020.
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English Version

Packaging for terminally sterilized medical devices - Part
2: Validation requirements for forming, sealing and
assembly processes (ISO 11607-2:2019)

Emballages des dispositifs médicaux stérilisés au stade
terminal - Partie 2: Exigences de validation pour les
procédés de formage, scellage et assemblage (ISO
11607-2:2019)

Verpackungen für in der Endverpackung zu
sterilisierende Medizinprodukte - Teil 2:
Validierungsanforderungen an Prozesse der
Formgebung, Siegelung und des Zusammenstellens
(ISO 11607-2:2019)

This European Standard was approved by CEN on 4 December 2019.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

This document (EN ISO 11607-2:2020) 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of an identical text or by endorsement, at the latest by July 2020, and conflicting national standards shall be withdrawn at the latest by July 2020.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 11607-2:2017.

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.

Endorsement notice

The text of ISO 11607-2:2019 has been approved by CEN as EN ISO 11607-2:2020 without any modification.

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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).

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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 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 11607-2:2006), which has been technically revised. It also incorporates the amendment ISO 11607-2:2006/Amd.1:2014.

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

- terms and definitions for “process variable”, “process parameter” and “monitoring of processes” have been added;
- various definitions have been aligned with the latest version of ISO 11139;
- the terminology of “critical” process parameters has been discontinued and the concept of a process specification has been 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.

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

Packaging for terminally sterilized medical devices 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 programme 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 document provides the framework of activities and requirements to develop and validate the process used to make and assemble the packaging system. Guidance for ISO 11607 series can be found in ISO/TS 16775.

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 health care facilities for use in internal sterilization are considered 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 document specifies requirements for the 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.

It is applicable to industry, to health care facilities, and to wherever medical devices are packaged and sterilized.

It does not cover all requirements for packaging medical devices that are manufactured aseptically. Additional requirements can be necessary for drug/device combinations.

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 11607-1:2018, *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

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]

3.2

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.]