

**LÕPLIKULT STERILISEERITUD MEDITSIINISEADME
PAKENDAMINE. OSA 1: NÕUDED MATERJALILE,
STERIILSELE BARJÄÄRILE JA PAKENDUSELE**

**Packaging for terminally sterilized medical devices -
Part 1: Requirements for materials, sterile barrier
systems and packaging systems (ISO 11607-1:2019 +
ISO 11607-1:2019/Amd 1:2023)**

EESTI STANDARDI EESSÕNA**NATIONAL FOREWORD**

See Eesti standard EVS-EN ISO 11607-1:2020+A11+A1:2023 sisaldab Euroopa standardi EN ISO 11607-1:2020 ja selle muudatuste A11:2022 ja A1:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11607-1:2020+A11+A1:2023 consists of the English text of the European standard EN ISO 11607-1:2020 and its amendments A11:2022 and A1:2023.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas. Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 15.01.2020, muudatus A11 15.06.2022 ja A1 25.10.2023.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation. Date of Availability of the European standard is 15.01.2020, for A11 15.06.2022 and A1 25.10.2023.
Muudatusega A11 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega A11 A11 . Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega A1 A1 . Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A11 is indicated in the text by tags A11 A11 . The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags A1 A1 . The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.30

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardimis- ja Akrediteerimiskeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardimis- ja Akrediteerimiskeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autoriõiguse kaitse kohta, võtke palun ühendust Eesti Standardimis- ja Akrediteerimiskeskusega: Koduleht www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation and Accreditation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation and Accreditation.

If you have any questions about standards copyright protection, please contact the Estonian Centre for Standardisation and Accreditation:

Homepage www.evs.ee; phone +372 605 5050; e-mail info@evs.ee

English Version

Packaging for terminally sterilized medical devices - Part
1: Requirements for materials, sterile barrier systems and
packaging systems (ISO 11607-1:2019 + ISO 11607-
1:2019/Amd 1:2023)

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 + ISO 11607-
1:2019/Amd 1:2023)

Verpackungen für in der Endverpackung zu
sterilisierende Medizinprodukte - Teil 1:
Anforderungen an Materialien, Sterilbarrieresysteme
und Verpackungssysteme (ISO 11607-1:2019 + ISO
11607-1:2019/Amd 1:2023)

This European Standard was approved by CEN on 3 November 2018. Amendment A11 was approved by CEN on 13 April 2022. Amendment A1 was approved by CEN on 12 September 2023.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard and its amendments 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.

This European Standard and its Amendments A11 and A1 exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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 11607-1:2009.

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 11607-1:2019 has been approved by CEN as EN ISO 11607-1:2020 without any modification.

A11 Amendment A11 European foreword

This document (EN ISO 11607-1:2020/A11:2022) 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 Amendment to the European Standard EN ISO 11607-1:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2022, and conflicting national standards shall be withdrawn at the latest by December 2022.

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

This document amends EN ISO 11607-1:2020 with a revised European Foreword and European Annexes ZA, ZB and ZC.

This Amendment to the European Standard EN ISO 11607-1:2020 has been prepared under a mandate 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, ZB and ZC, which are an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN websites.

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, ZB or ZC’, 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
ISO 11607-2	EN ISO 11607-2:2020	ISO 11607-2:2019

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, Republic of North Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom. ^(A11)

A1 Amendment A1 European foreword

This document (EN ISO 11607-1:2020/A1:2023) 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 Amendment to the European Standard EN ISO 11607-1:2020 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2024, and conflicting national standards shall be withdrawn at the latest by April 2024.

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 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) / Regulation(s).

For relationship with EU Directive(s) / Regulation(s), see informative Annex ZA and Annex ZB, which are integral parts of this document.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 11607-1:2019/Amd 1:2023 has been approved by CEN as EN ISO 11607-1:2020/A1:2023 without any modification. **A1**

This document is a preview generated by EVS

Contents

Page

Foreword	v
[A1] Amendment A1 foreword [A1]	vi
Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General requirements	7
4.1 Quality systems	7
4.2 Risk management	7
4.3 Sampling	7
4.4 Test methods	8
4.5 Documentation	8
5 Materials, preformed sterile barrier systems and sterile barrier systems	8
5.1 General requirements	8
5.2 Microbial barrier properties	12
5.3 Compatibility with the sterilization process	12
5.4 Labelling system	13
5.5 Storage and transport of materials and preformed sterile barrier systems	13
6 Design and development for packaging systems	13
6.1 General	13
6.2 Design	14
7 Usability evaluation for aseptic presentation	15
8 Packaging system performance and stability	16
8.1 General	16
8.2 Packaging system performance testing	16
8.3 Stability testing	17
9 Packaging system validation and changes	17
10 Inspection immediately prior to aseptic presentation	18
11 Information to be provided	18
Annex A (informative) Guidance on medical packaging	19
Annex B (informative) Standardized test methods, guides and procedures that can be used to demonstrate conformity with the requirements of this document	22
Annex C (normative) Test method for resistance of impermeable materials to the passage of air	33
Annex D (informative) Environmental aspects	34
Annex E (informative) Draft guidance on ways to differentiate a sterile barrier system from protective packaging	35
[A1] Annex F (normative) Risk management [A1]	40
[A1] Annex G (informative) Risk management for medical device packaging — Rationale for requirements [A1]	44
[A1] Annex ZA (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered [A1]	54

Annex ZB (informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered	58
Annex ZC (informative) Relationship between this European Standard and the essential requirements of Directive 98/79/EC [OJ L 331] (as amended) aimed to be covered	62
Bibliography	64

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.

A1 Amendment A1 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 102, *Sterilizers for medical purposes*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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. **A1**

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 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 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.

This document is a preview generated by EVS

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.

A1 *deleted text* **A1**

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.

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*

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]

3.2

bioburden

population of viable microorganisms on or in product and/or sterile barrier system