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Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing

EESTI STANDARDIMIS- JA AKREDITEERIMISKESKUS
ESTONIAN CENTRE FOR STANDARDISATION AND ACCREDITATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 13060:2025 sisaldab Euroopa standardi EN 13060:2025 ingliskeelset teksti.	This Estonian standard EVS-EN 13060:2025 consists of the English text of the European standard EN 13060:2025.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 27.08.2025.	Date of Availability of the European standard is 27.08.2025.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	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.

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EUROPEAN STANDARD

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English Version

Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing

Stérilisateurs à usage médical - Petits stérilisateurs à la vapeur d'eau - Exigences et essais

Sterilisatoren für medizinische Zwecke - Dampf-Klein-Sterilisatoren - Anforderungen und Prüfung

This European Standard was approved by CEN on 23 June 2025.

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.

This European Standard exists 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, Türkiye and United Kingdom.

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

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European foreword

This document (EN 13060:2025) 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 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 February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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 13060:2014+A1:2018.

In comparison with the previous edition, the following technical modifications have been made:

— the structure of the main text has been widely adopted to the structure of ISO/TS 22421:2021;

— update of normative references;

— update of terms and definitions to align with EN ISO 11139:2018 and EN ISO 11139:2018/A1:2024;

— for requirement on non-condensable gases test, reference is made to EN 285:2015+A1:2021;

— considerations of aspect of standardization in moist heat sterilization to align with EN ISO 17665:2024.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

In this document, the following verbal forms are used:

— “shall” indicates a requirement;

— “should” indicates a recommendation;

— “may” indicates a permission;

— “can” indicates a possibility or capability; and

— “must” is used to express an external constraint.

In this document notes are used for giving additional information intended to assist the understanding or use of the text of document. The document shall be usable without the notes.

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

According to the CEN-CENELEC Internal Regulations, the national standards organisations 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.

Introduction

Small steam sterilizers are widely used for medical purposes, e.g. in general medical practice, dentistry, podiatry, facilities for personal hygiene and beauty care and also veterinary practice. They are also used for materials and equipment which are likely to come into contact with blood or bodily fluids, e.g. implements used by beauty therapists, tattooists, body piercers and hairdressers. The specific nature of such loads used within these fields of application call for different performance requirements for the sterilization cycles and hence different corresponding test methods.

This document provides minimum requirements for small steam sterilizers and associated test methods. Performance is defined by reference to standard test loads. These are used to define a basic minimum performance and are not necessarily related to specific medical devices. It is the responsibility of the user and the manufacturer of the device to be sterilized to determine that any particular cycle is suitable for sterilizing a particular device. The performance tests specified in this document can also be used by the manufacturer of the device to be sterilized to specify the appropriate performance for decontamination processes according to the requirements for information to be given by medical device manufacturers according to EN ISO 17664-1. This will enable users to identify the specific sterilizer performance required to safely process their devices.

The performance requirements specified in this document are not intended for the process to be effective in inactivating the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease. However, some national regulations require the use of modified steam processes as part of a general prion decontamination programme.

It is essential that the sterilizer and ancillary equipment is used only for the sterilization of the type of products for which it is designed. The choice of sterilizer, sterilization cycle or quality of services provided can be inappropriate for a particular product. Therefore, the suitability of a sterilization procedure for a particular product is verified by validation, see EN ISO 17665. Conformance with these requirements for development, validation and routine control of sterilization process ensures that the sterilization process is both reliable and reproducible so that predictions can be made, with reasonable confidence, that there is low probability of there being a viable microorganism present on a health care product after sterilization.

1 Scope

This document specifies the performance requirements and test methods for small steam sterilizers and sterilization cycles which are used for medical purposes or for materials that are likely to come into contact with blood or body fluids.

This document applies to automatically controlled small steam sterilizers that generate steam using electrical heaters or use steam that is generated by a system external to the sterilizer.

This document applies to small steam sterilizers used primarily for the sterilization of medical devices with a chamber volume of less than 60 l and unable to accommodate a sterilization module (300 mm × 300 mm × 600 mm).

The requirements concerning the quality management and risk management are addressed by other standards (e.g. EN ISO 13485, EN ISO 14971).

This document does not apply to small steam sterilizers that are used to sterilize liquids or pharmaceutical products.

This document does not specify safety requirements related to risks associated with the zone in which the sterilizer is used (e.g. flammable gases).

This document does not specify requirements for the validation and routine control of sterilization by moist heat.

NOTE Requirements for the validation and routine control of sterilization by moist heat are given in EN ISO 17665.

This document does not specify requirements for other sterilization processes that also employ moist heat as part of the process (i.e. formaldehyde, ethylene oxide).

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.

EN 285:2015+A1:2021, *Sterilization — Steam sterilizers — Large sterilizers*

EN 556-1:2024, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

EN 764-7:2002,[1] *Pressure equipment — Part 7: Safety systems for unfired pressure equipment*

EN 868-2:2025, *Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods*

EN 868-4:2025, *Packaging for terminally sterilized medical devices — Part 4: Paper bags — Requirements and test methods*

EN 868-5:2018, *Packaging for terminally sterilized medical devices — Part 5: Sealable pouches and reels of porous materials and plastic film construction — Requirements and test methods*

EN 10088-1:2023, *Stainless steels — Part 1: List of stainless steels*

[1] This document is impacted by corrigendum EN 764-7:2002/AC:2006.

EN 13445-1:2021, *Unfired pressure vessels — Part 1: General*

EN 13445-2:2021+A1:2023, *Unfired pressure vessels — Part 2: Materials*

EN 13445-3:2021, *Unfired pressure vessels — Part 3: Design*

EN 13445-4:2021+A1:2023, *Unfired pressure vessels — Part 4: Fabrication*

EN 13445-5:2021+A1:2024, *Unfired pressure vessels — Part 5: Inspection and testing*

EN 13445-8:2021, *Unfired pressure vessels — Part 8: Additional requirements for pressure vessels of aluminium and aluminium alloys*

EN 60529:1991,[2] *Degrees of protection provided by enclosures (IP Code)*

EN 61010-1:2010,[3] *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*

EN 62366-1:2015,[4] *Medical devices — Part 1: Application of usability engineering to medical devices*

EN IEC 60751:2022, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2022)*

EN IEC 61010-2-040:2021, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2020)*

EN IEC 61326-1:2021, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements (IEC 61326-1:2020)*

EN ISO 228-1:2003, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation (ISO 228-1:2000)*

EN ISO 4017:2022, *Fasteners — Hexagon head screws — Product grades A and B (ISO 4017:2022)*

EN ISO 4126-1:2013,[5] *Safety devices for protection against excessive pressure — Part 1: Safety valves (ISO 4126-1:2013)*

EN ISO 11138-3:2017, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2017)*

EN ISO 11140-1:2014, *Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2014)*

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[2] This document is impacted by amendment EN 60529:1991/A1:2000 and EN 60529:1991/A2:2013, with corrigendum EN 60529:1991/A2:2013/AC:2019-02, and corrigendum EN 60529:1991/AC:2016-12.

[3] This document is impacted by amendment EN 61010-1:2010:2010/A1:2019 and corrigendum EN 61010-1:2010/A1:2019/AC:2019.

[4] This document is impacted by corrigenda EN 62366-1:2015/AC:2015 and EN 62366-1:2015/AC:2016-09 and amendment EN 62366-1:2015/A1:2020.

[5] This document is impacted by amendments EN ISO 4126-1:2013/A1:2016 and EN ISO 4126-1:2013/A2:2019.

EN ISO 11140-6:2022, *Sterilization of health care products — Chemical indicators — Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers (ISO 11140-6:2022)*

EN ISO 14971:2019,[6] *Medical devices — Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 17665:2024, *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)*

EN ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer (ISO 20417:2021, Corrected version 2021-12)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
access device
means by which entry to restricted parts of equipment is achieved

Note 1 to entry: This can be by dedicated key, code, or tool.

[SOURCE: EN ISO 11139:2018, 3.4]

3.2
active drain
drain through which fluids present in the chamber are discharged during the process

3.3
automatic controller
device that directs the equipment sequentially through required stages of the cycle in response to programmed *cycle parameters*

[SOURCE: EN ISO 11139:2018, 3.18]

3.4
biological indicator
test system containing viable microorganisms providing a specified resistance to a specified *sterilization process*

[SOURCE: EN ISO 11139:2018, 3.29]

[6] This document is impacted by amendment EN ISO 14971:2019/A11:2021.