SLOVENSKI STANDARD
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Nadomešča:
SIST EN 13060:2015+A1:2019

Sterilizatorji za uporabo v medicini - Mali parni sterilizatorji - Zahteve in preskušanje

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

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

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

Ta slovenski standard je istoveten z: **prEN 13060**

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11.080.10	Sterilizacijska oprema	Sterilizing equipment

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English Version

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

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

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

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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

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Contents

Page

European foreword

This document (prEN 13060:2023) 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 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;

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

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, which is an integral part of this document.

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 specifies the general 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 needs to be 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 556-1:2001, *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 868-2:2017, *Packaging for terminally sterilized medical devices — Part 2: Sterilization wrap — Requirements and test methods*

EN 868-4:2017, *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*

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

EN 10088-1:2014, *Stainless steels — Part 1: List of stainless steels*

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

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

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

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

EN 13445-5:2021, *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 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[4], *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 amendment 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[5], *Medical devices — Application of risk management to medical devices (ISO 14971:2019)*

EN ISO 17665:—[6], *Sterilization of health care products — Moist heat — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO/DIS 17665:2022)*

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]

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5 This document is impacted by amendment EN ISO 14971:2019/A11:2021.

6 Under preparation. Stage at the time of publication: prEN ISO/DIS 17665:2022.

3.5
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: EN ISO 11139:2018, 3.31]

3.6
chamber
part of equipment in which a load is processed

[SOURCE: EN ISO 11139:2018, 3.36]

3.7
chemical indicator
test system that reveals change in one or more pre-specified *process variables* based on a chemical or physical change resulting from exposure to a process

Note 1 to entry: An indicator intended to be used only in combination with a specific test load is also termed an indicator (both together becoming an indicator system).

[SOURCE: EN ISO 11139:2018, 3.43, modified – Note 1 to entry has been added]

3.8
control
regulation of variables within specified limits

[SOURCE: EN ISO 11139:2018, 3.63]

3.9
cycle complete
message from the automatic controller that the operating cycle has ended successfully

[SOURCE: EN ISO 11139:2018, 3.71]

3.10
cycle parameter
value of a *cycle variable* including its tolerance used for *control*, *monitoring*, indication, and recording of an operating cycle

[SOURCE: EN ISO 11139:2018, 3.72]

3.11
cycle variable
property used to *control*, monitor, indicate, or record an *operating cycle*

[SOURCE: EN ISO 11139:2018, 3.74]

3.12
double-ended
having separate doors for loading and unloading in separate areas

[SOURCE: EN ISO 11139:2018, 3.92]

3.13
equilibration time
period between the attainment of defined sterilization process parameters at the reference measurement point and the attainment of the specified sterilization process parameters at all points within the load

Note 1 to entry: For the purpose of this document, the process parameter to which this definition refers is temperature.

[SOURCE: EN ISO 11139:2018, 3.105, modified – Note 1 to entry has been added]

3.14
equipment maintenance
combination of all technical and associated administrative actions intended to keep equipment at a state in which it can perform its required function, or restore it to such a state

[SOURCE: EN ISO 11139:2018, 3.106]

3.15
exposure phase
cycle stage between the introduction of the sterilizing or disinfecting agent into the *chamber* and when the agent is removed

Note 1 to entry: Disinfecting agent does not concern steam sterilization. For the purpose of this document the sterilizing agent is moist heat and the exposure phase corresponds to the plateau period which is used in EN 13060.

[SOURCE: EN ISO 11139:2018, 3.111, modified – Note 1 to entry has been added]

3.16
fault
situation in which one or more of the process or *cycle parameters* is/are outside its/their specified tolerance(s)

[SOURCE: EN ISO 11139:2018, 3.116]

3.17
hazard
potential source of harm

[SOURCE: EN ISO 11139:2018, 3.130]

3.18
hazardous situation
circumstance in which people, property, or the environment is/are exposed to one or more *hazards*

[SOURCE: EN ISO 11139:2018, 3.131]

3.19
holding time
<small steam sterilizer> period for which the temperatures at all points within the useable chamber space and the load are continuously within the sterilization temperature band

Note 1 to entry: The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

[SOURCE: EN ISO 17665:—[6], 3.26, modified: "<small sterilizers>" added, "at the reference measurement point and" deleted and "within the sterilization load" replaced by "within the usable chamber space and the load]

3.20
installation test
series of checks and tests performed during installation of the sterilizer in the place of use

3.21
load
product, equipment, or materials to be processed together within an *operating cycle*

[SOURCE: EN ISO 11139:2018, 3.155]

3.22
load configuration
distribution and orientation of a *load*

[SOURCE: EN ISO 11139:2018, 3.156]

3.23
loading door
means of access through which a *load* is passed into the chamber before processing

[SOURCE: EN ISO 11139:2018, 3.157]

3.24
locked
with the interlock(s) fully engaged

3.25
maximum allowable pressure
PS
maximum pressure for which the equipment is designed as specified by the manufacturer

[SOURCE: EN 764-1:2015+A1:2016, 3.2.87]

3.26
measurement uncertainty
non-negative parameter characterizing the dispersion of the quantity values being attributed to a measurand, based on the information used

[SOURCE: EN ISO 11139:2018, 3.164]