SLOVENSKI STANDARD
oSIST prEN 14180:2023

01-junij-2023

Nadomešča:
SIST EN 14180:2014

Sterilizatorji za uporabo v medicini - Sterilizatorji s paro z nizko temperaturo in s formaldehidom - Zahteve in preskušanje

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren - Anforderungen und Prüfung

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

Ta slovenski standard je istoveten z: **prEN 14180**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

oSIST prEN 14180:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 14180

April 2023

ICS 11.080.10

Will supersede EN 14180:2014

English Version

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Dampf-Formaldehyd-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.

This draft European Standard was established by CEN 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.

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.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

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

Contents

Page

European foreword

This document (prEN 14180:2023) 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 14180:2014.

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.

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

— structure of the main text has been adapted to the structure of ISO/TS 22421:2021 and harmonized with the current revisions of EN 17180 and EN 1422 in 2022;

— references have been updated, including Table H.1 on Environmental Aspects, and the bibliography;

— some definitions of terms have been added, most definitions have been adapted with reference to EN ISO 11139:2018;

— a separate clause ‘Protective measures’ has been implemented for referencing to individual clauses of EN IEC 61010-2-040:2021;

— a new Annex G ‘Alternative protective measures’ has been added;

— requirements on the control and monitoring system have been merged into a new clause and informative illustrations have been provided in a new Annex F;

— an informative new Annex E ‘Application of Formaldehyde in LTSF-processes.’ has been added to explain in some detail the physico-chemical specifics during operation of the sterilizer;

— the specifications provide as a new option a specific cycle for simple items and a ‘simple items test load’ to allow (shorter) cycles for load configurations providing a lower challenge to the sterilization process regarding sterilizing agent penetration, desorption and total mass of the load;

— a new Annex I ‘Technical information and documentation’ has been added to consider Annex II of the European Medical Device Regulation (MDR);

— a new Annex ZA has been added to show the relationship between this European Standard and applicable European Directives and European Regulations.

Introduction

This document provides minimum requirements and test methods for sterilizers working below ambient atmospheric pressure performing a low temperature steam and formaldehyde (LTSF) process.

LTSF sterilizers typically use a mixture of steam and formaldehyde at thermodynamic equilibrium conditions. Sterilization occurs in the condensate layer at the surface of the items to be sterilized.

LTSF sterilizers are primarily used for the sterilization of medical devices in health care facilities but may also be used during the commercial production of medical devices.

LTSF processes are specified by physical parameters and verified using physical, chemical and microbiological means [12]. The sterilizers operate automatically using pre-set cycles.

The test methods and test equipment given may also be applicable to validation and routine control.

Validation and routine control of sterilization processes are essential to ensure their efficacy. This document does not cover validation and routine control of a LTSF process. Criteria for validation and routine control of LTSF sterilization processes are given in EN ISO 25424.

At the present state of knowledge, LTSF sterilizers should not be assumed to deliver processes effectively inactivating the causative agents of spongiform encephalopathies such as scrapie, Bovine Spongiform Encephalopathy and Creutzfeldt-Jakob Disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents. See also EN ISO 25424:2019, 1.2.1.

Planning and design of products applying to this standard should consider not only technical issues but also the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex H of this document.

General safety requirements for sterilizers are specified by EN 61010-1, and EN IEC 61010-2-040. Further, EN 60204-1 can provide valuable options. They are referenced herein, but not repeated. Occupational safety is not addressed in this document.

1 Scope

1.1 This document specifies requirements and tests for LTSF sterilizers, which use a mixture of low temperature steam and formaldehyde as sterilizing agent, and which are working below ambient pressure only.

These sterilizers are primarily used for the sterilization of heat labile medical devices in health care facilities.

1.2 This document specifies minimum requirements:

— for the performance and design of sterilizers intended to deliver an LTSF-process capable of sterilizing medical devices;

— for the equipment and controls of these sterilizers needed for operation, control and monitoring of the sterilization processes, and which can be used for validation of the sterilization process.

1.3 This document specifies further test equipment and test procedures used to verify conformance of the equipment design and performance specified by this document.

1.4 This document does not specify requirements and tests for decontamination systems for use in rooms, enclosures, or environmental spaces.

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

EN 867-5:2001, *Non-biological systems for use in sterilizers — Part 5: Specification for indicator systems and process challenge devices for use in performance testing for small sterilizers Type B and Type S*

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 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 14222:2021, *Stainless steel steam boilers*

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

EN 60204-1:2018, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements (IEC 60204-1:2016, modified)*

EN 60584-1:2013, *Thermocouples — Part 1: EMF specifications and tolerances (IEC 60584-1:2013)*

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

EN 61010-1:2010[2], *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*

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 62366-1:2015, Medical devices — Part 1: Application of usability engineering to medical devices[3]

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 11138-1:2017, *Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2017)*

EN ISO 11138-5:2017, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2017)*

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 12100:2010, *Safety of machinery — General principles for design — Risk assessment and risk reduction (ISO 12100:2010)*

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

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

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 3746:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

3 Terms and definitions

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

[2] This document is impacted by the amendment EN 61010-1:2010/A1:2019 and corrigendum EN 61010-1:2010/A1:2019/AC:2019-04.

[3] This document is impacted by a corrigendum EN 62366-1:2015/AC:2015 and the amendment EN 62366-1:2015/A1:2020.

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 a dedicated key, code or tool.

[SOURCE: EN ISO 11139:2018, 3.4]

3.2
aeration
part of the sterilization process during which the sterilizing agent and/or its reaction products desorb from the health care product until predetermined levels are reached

[SOURCE: EN ISO 11139:2018, 3.7]

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]

3.5
chamber
part of equipment in which load is processed

Note 1 to entry: In this document, the chamber is the “sterilizer chamber”.

[SOURCE: EN ISO 11139:2018, 3.36, modified – Note 1 to entry added.]

3.6
chamber pre-heating
process that raises the temperature of internal chamber surfaces prior to the commencement of an operating cycle

[SOURCE: EN ISO 11139:2018, 3.37]

3.7
chamber volume
enclosed space of a chamber, including the volume of nozzles to the first connection or weld, and excluding the volume of permanent internal parts

[SOURCE: EN ISO 11139:2018, 3.318.1]

3.8
conditioning
treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load

[SOURCE: EN ISO 11139:2018, 3.58]

3.9
control
regulation of variables within specified limits

[SOURCE: EN ISO 11139:2018, 3.63]

3.10
cycle complete
message from the automatic controller that the operating cycle has ended successfully

[SOURCE: EN ISO 11139:2018, 3.71]

3.11
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]

3.12
cycle variable
property used to control, monitor, indicate, or record an operating cycle

[SOURCE: EN ISO 11139:2018, 3.74]

3.13
desorption
removal of the sterilizing agent from the chamber and the load at the end of the exposure phase

[SOURCE: EN ISO 11139:2018, 3.78]

3.14
development
act of elaborating a specification

[SOURCE: EN ISO 11139:2018, 3.79]

3.15
double-ended
having separate doors for loading and unloading in separate areas

[SOURCE: EN ISO 11139:2018, 3.92]

3.16
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

[SOURCE: EN ISO 11139:2018, 3.105]

3.17
establish
determine by theoretical evaluation and confirm by experimentation

[SOURCE: EN ISO 11139:2018, 3.107]

3.18
exposure phase
cycle stage between the introduction of the sterilizing or disinfecting agent into the chamber and when the agent is removed

[SOURCE: EN ISO 11139:2018, 3.111]

3.19
F_{BIO} **value**
expression of the resistance of a biological indicator calculated as the product of the logarithm of the initial population of microorganisms and the *D* value

[SOURCE: EN ISO 11139:2018, 3.113.2]

3.20
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]

3.21
filter
construct of porous material through which a fluid is passed to remove viable and/or non-viable particles

[SOURCE: EN ISO 11139:2018, 3.117]

3.22
hazard
potential source of harm

[SOURCE: EN ISO 11139:2018, 3.130]

3.23
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]

3.24
holding time
period during which process parameters are maintained, within their specified tolerances

[SOURCE: EN ISO 11139:2018, 3.133]

3.25
indicate
display a value, condition, or stage of process

[SOURCE: EN ISO 11139:2018, 3.139]

3.26
installation qualification
IQ
process of establishing by objective evidence that all key aspects of a process equipment and ancillary system installation comply with the approved specification

[SOURCE: EN ISO 11139:2018, 3.220.2]

3.27
load
product, equipment, or materials to be processed together within an operating cycle

[SOURCE: EN ISO 11139:2018, 3.155]

3.28
load configuration
distribution and orientation of a load

[SOURCE: EN ISO 11139:2018, 3.156]

3.29
loading door
means of access through which a load is passed into the chamber before processing

[SOURCE: EN ISO 11139:2018, 3.157]

3.30
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use or software material, or other similar related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,