SLOVENSKI STANDARD
oSIST prEN 17180:2023

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

Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Sterilisatoren mit verdampftem Wasserstoffperoxid - Anforderungen und Prüfverfahren

Stérilisateurs à usage médical Stérilisateurs à la vapeur de peroxyde dhydrogène à basse température Exigences et essais

Ta slovenski standard je istoveten z: **prEN 17180**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

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EUROPEAN STANDARD

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ICS

English Version

Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing

Stérilisateurs à usage médical ¿ Stérilisateurs à la vapeur de peroxyde d¿hydrogène à basse température ¿ Exigences et essais

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Sterilisatoren mit verdampftem Wasserstoffperoxid - Anforderungen und Prüfverfahren; Deutsche und Englische Fassung PWI EN 17180:2019

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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European foreword

This document (prEN 17180:2023) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

A first draft (prEN 17180:2017) was published in 2017, but the status of the project was set back to a preliminary work item. The following changes were made to the first draft:

— the structure of the main text has been widely adapted to the structure of ISO/TS 22421:2021 and harmonized with the current revisions of EN 14180 and EN 1422 in 2022;

— 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 and an Annex G ‘protective measures’ has been created;

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

— an Annex J ‘Technical information and documentation’ has been added to consider Annex II of the European Medical Device Regulation (MDR).

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 Regulation(s).

For relationship with EU Regulation(s), see informative Annex ZA, which is an integral part of this document.

Introduction

This document specifies minimum requirements and test methods for sterilizers performing a low temperature sterilization process using a composition of water and hydrogen peroxide (H_2O_2), vaporized, and injected into the sterilizer chamber as sterilizing agent. Vaporized hydrogen peroxide (H_2O_2) sterilizers process typically below 60°C and are primarily used for the sterilization of thermolabile or moisture-sensitive medical devices in health care facilities but can also be used for sterilization of other reusable medical devices that have been established to be compatible with VH2O2 processes. The sterilizers operate automatically using pre-set cycles. VH2O2 sterilizers can also be used by medical device manufacturers during commercial production.

Like the other standardized low temperature sterilization processes using ethylene oxide (EN 1422 and EN ISO 11135) or low temperature steam and formaldehyde (EN 14180 and EN ISO 25424), the VH2O2 sterilization processes are specified by physical and chemical parameters and verified using physical, chemical, and microbiological means. The sterilizers operate automatically using pre-set cycles.

The tests described in this document are reference tests intended to demonstrate conformity with the performance requirements specified in this document. They may be used in type tests, works tests, in validation and re-qualification, or in periodic and routine tests carried out by the user. Validation and routine control of sterilization processes are essential to ensure their efficacy. This document does not cover validation and routine control of a VH2O2 sterilization process. EN ISO 14937 provides general requirements and guidance on validation and routine control of such processes. ISO 22441 provides specific requirements for validation and routine control of VH2O2 sterilization.

Some VH2O2 sterilizers have processes that demonstrate some level of inactivation of the causative agents of spongiform encephalopathies such as scrapie, bovine spongiform encephalopathy, and Creutzfeldt-Jakob Disease. However, this inactivation is process, cycle, and test protocol specific, and not equipment specific, therefore this inactivation is not addressed in this document, and no specific test methods are provided.

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

NOTE Specifications on general equipment safety are addressed in EN 61010-1, EN IEC 61010-2-040, and are not repeated in this document. EN 60204-1 can also apply (see Annex G). Requirements on occupational safety and health are not specified in this document. National regulations can exist.

1 Scope

This document specifies requirements and tests for low temperature hydrogen peroxide sterilizers, using vaporized aqueous solution of hydrogen peroxide as the sterilizing agent.

These sterilizers are used for the sterilization of medical devices, particularly thermolabile medical devices.

This document specifies minimum requirements:

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

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

— for the test equipment and test procedures used to verify the sterilizer performance specified by this document.

This document does not specify requirements for equipment intended to process liquids, biological waste, or human tissues unless part of a medical device.

This document does not describe a quality management system for the control of all stages of the manufacture of the sterilizer.

NOTE Attention is drawn to the standards for quality management, e.g. EN ISO 13485.

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 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 868-9:2018, *Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods*

EN 60204-1:2018, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements*

EN 60584-1:2013, *Thermocouples - Part 1: EMF specifications and tolerances*

EN 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements*

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

EN 62366-1:2015/A1:2020, *Medical devices - Part 1: Application of usability engineering to medical devices*

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

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*

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)*

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

EN ISO 11607-1:2020, *Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)*

EN ISO 11607-2:2020, *Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)*

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

EN ISO 15223-1:2021, *Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)*

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

ISO 2861:2020, *Vacuum technology — Dimensions of clamped-type quick-release couplings*

ISO 22441:2022, *Sterilization of health care products — Low temperature vaporized hydrogen peroxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

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:

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://www.iso.org/obp

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
accompanying information
information accompanying or marked on a sterilizer and containing information for the user or those accountable for the installation, use, maintenance, decommissioning and disposal of the sterilizer, particularly regarding safe use

Note 1 to entry: The accompanying information can be regarded as part of the sterilizer.

Note 2 to entry: The accompanying information can consist of the *label* (see 3.29), marking, instructions for use, technical description, installation manual, quick reference guide, etc.

Note 3 to entry: Accompanying information is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g. CD/DVD-ROM, USB stick, website).

[SOURCE: EN ISO 20417:2021, 3.2, modified — "Medical device or accessory" has been changed to "sterilizer", the term "processing" has been removed, Note 1 to entry has been modified to exclude a requirement and Note 4 to entry has been deleted.]

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 BI
test system containing viable microorganisms providing a specified resistance to a specified sterilization process

[SOURCE: EN ISO 11139:2018, 3.29]

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 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
chemical indicator
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

[SOURCE: EN ISO 11139:2018, 3.43]

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

Note 1 to entry: In this document conditioning is used as conditioning stage

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

[SOURCE: EN ISO 11139:2018, 3.92]

3.15
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]

3.16
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]

3.17
establish
determine by theoretical evaluation and confirm by experimentation

[SOURCE: EN ISO 11139:2018, 3.107]

3.18
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]

3.19
filter

construct of porous material through which a *fluid* (3.20) is passed to remove viable and/or non-viable particles

[SOURCE: EN ISO 11139:2018, 3.117]

3.20
fluid
substance that continually deforms (flows) under applied shear force

EXAMPLE Liquid, gas, vapour, plasma

[SOURCE: EN ISO 11139:2018, 3.120]

3.21
hazard
potential source of harm

[SOURCE: EN ISO 11139:2018, 3.130]

3.22
hazardous situation
circumstance in which people, property, or the environment is/are exposed to one or more *hazards* (3.21)

[SOURCE: EN ISO 11139:2018, 3.131]