SLOVENSKI STANDARD
oSIST prEN 17180:2018

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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 vaporized 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 d'hydrogène à basse température - Exigences et essais

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

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

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European foreword

This document (prEN 17180:2017) 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.

This document 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 Annex ZA, which is an integral part of this document.

This document is a working document provided by DIN mirror group for gas sterilizer as a new work item proposal.

The following referenced documents are indispensable for the application of this document. For undated references, the edition of the referenced document (including any amendments) listed below applies. For dated references, only the edition cited applies. However, for any use of this standard within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.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 should 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.

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**
ISO 2861	---	ISO 2861:2013

Introduction

This European Standard specifies minimum requirements and test methods for sterilizers processing, typically, below 80 °C, performing a low temperature sterilization process using a composition of water and hydrogen peroxide (H_2O_2) as sterilizing agent, vaporized and injected into the sterilizer chamber. Vaporized hydrogen peroxide (VH_2O_2) sterilizers are primarily used for the sterilization of thermolabile medical devices in health care facilities, but can also be used during commercial production of medical devices.

Like the other standardized low temperature sterilization processes using ethylene oxide (see EN 1422 and EN ISO 11135) or low temperature steam and formaldehyde (see EN 14180 and EN ISO 25424) the VH_2O_2 sterilization processes are specified by physical and chemical parameters and verified using physical, chemical and microbiological means [*ref*]. The sterilizers operate automatically using pre-set cycles.

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

Validation and routine control of sterilization processes are essential to ensure their efficacy. This standard does not cover validation and routine control of a VH_2O_2 sterilization process. Harmonized standards providing specific requirements for validation and routine control of VH_2O_2 sterilization processes are currently not available. EN ISO 14937 can provide general requirements and guidance on how to perform validation and routine control of such processes.

Some VH_2O_2 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 outside the scope of this European Standard, and no specific test methods are provided [*ref*].

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 standard.

NOTE Specifications on operators safety are addressed in EN 61010-1, EN 61010-2-040 and are not repeated in this standard. FprEN 60204-1 can also apply (see Annex G).

1 Scope

This European Standard specifies requirements and tests for low temperature hydrogen peroxide sterilizers, which use a 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 European Standard 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 European Standard.

This European Standard does not specify requirements for equipment intended to process liquids, biological waste or human tissues.

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

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

NOTE 1 Attention is drawn to the standards for quality management, e.g. EN ISO 13485.

NOTE 2 Environmental aspects of this standard are addressed in Annex H.

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 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 868-5:2009, *Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods*

EN 868-9:2009, *Packaging for terminally sterilized medical devices - Part 9: Uncoated nonwoven materials of polyolefines - Requirements and test methods*

FprEN 60204-1:2016, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements (IEC/FDIS 60204-1:2016)*

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

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

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

EN 61010-2-040:2015, *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 61010-2-040:2015)*

EN 61326-1:2013, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements (IEC 61326-1:2012)*

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 11607-1:2009/A1:2014, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006/Amd 1:2014)*

EN ISO 11607-2:2009/A1:2014, *Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006/Amd 1:2014)*

EN ISO 14937:2009, *Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)*

EN ISO 14971:2012, *Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 15223-1:2016, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)*

ISO 2861:2013, *Vacuum technology - Dimensions of clamped-type quick-release couplings*

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 http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
aeration
part of the sterilization cycle during which the sterilizing agent and/or its reaction products desorb from the medical device until predetermined levels are reached

[SOURCE: prEN ISO 11139:2017, term 3.7]

3.2
automatic controller
device that directs the equipment sequentially through required stages of the cycle in response to programmed cycle parameters

[SOURCE: prEN ISO 11139:2017, term 3.18]

3.3
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[SOURCE: prEN ISO 11139:2017, term 3.29]

3.4
chamber
part of equipment in which a load is processed

[SOURCE: prEN ISO 11139:2017, term 3.36]

3.5
chamber pre-heating
raising the temperature of internal chamber surfaces prior to the commencement of an operating cycle

[SOURCE: prEN ISO 11139:2017, term 3.37]

3.6
conditioning
treatment of product prior to the exposure phase to attain a specified temperature, relative humidity, or other process variable throughout the load

[SOURCE: prEN ISO 11139:2017, term 3.57]

3.7
cycle complete
message from the automatic controller that the operating cycle has ended successfully

[SOURCE: prEN ISO 11139:2017, term 3.72]

3.8
cycle parameter
value of a cycle variable including its tolerances used for control, monitoring, indication and recording of an operating cycle

[SOURCE: prEN ISO 11139:2017, term 3.74]

3.9
cycle variable
property used to control, monitor, indicate, or record an operating cycle

Note 1 to entry: For VH_2O_2-sterilizers, the cycle variables include, but are not necessarily limited to temperature, pressure, time, Sterilant concentration.

[SOURCE: prEN ISO 11139:2017, term 3.76]

3.10
desorption
removal of the sterilizing agent from the chamber and the load at the end of the exposure phase

[SOURCE: prEN ISO 11139:2017, term 3.80]

3.11
double-ended
having separate doors for loading and unloading in separate areas

[SOURCE: prEN ISO 11139:2017, term 3.92]

3.12
fault
situation in which one or more of the process or cycle parameters is/are outside its/their specified tolerance(s)

[SOURCE: prEN ISO 11139:2017, term 3.116]

3.13
holding time
period during which process parameters are maintained in the load, within their specified tolerances

[SOURCE: prEN ISO 11139:2017, term 3.133]

3.14
installation qualification
IQ
process of establishing by objective evidence that all key aspects of the process equipment and ancillary system installation comply with the approved specification

[SOURCE: prEN ISO 11139:2017, term 3.223.2]

3.15
load
product, equipment or materials to be processed together within an operating cycle

[SOURCE: prEN ISO 11139:2017, term 3.155]

3.16
measuring chain
series of elements of a measuring instrument or measuring system, which constitutes the path of the measurement signal from the input (quantity subject to measurement) to the output (the result of the measurement)

[SOURCE: prEN ISO 11139:2017, term 3.165]

3.17
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use or calibrator, 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;
- disinfection of medical devices;
- providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include:

- items specifically intended for cleaning or sterilization of medical devices;
- pouches, reel goods, sterilization wrap, and reusable containers for packaging of medical devices for sterilization;
- disinfection substances;
- aids for persons with disabilities;
- devices incorporating animal and/or human tissues;
- devices for in vitro fertilization or assisted reproduction technologies.

[SOURCE: prEN ISO 11139:2017, term 3.166]

3.18
monitoring
continual checking, supervising, critically observing or determining the status in order to identify change from the performance level required or expected

[SOURCE: prEN ISO 11139:2017, term 3.180]

3.19
operating cycle
complete set of stages of a process, carried out in a specified sequence

[SOURCE: prEN ISO 11139:2017, term 3.188]

3.20
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[SOURCE: prEN ISO 11139:2017, term 3.223.3]

3.21
override
system by which an operating cycle can be interrupted or modified as necessary

[SOURCE: prEN ISO 11139:2017, term 3.191]

3.22
process challenge device
PCD
item providing a defined resistance to a cleaning, disinfection, or sterilization process and used to assess performance of the process

Note 1 to entry: The device is so constituted that a biological or chemical indicator can be put in the place which is the most difficult to reach by sterilizing agent(s) and does not interfere with the function of the process challenge device.

[SOURCE: prEN ISO 11139:2017, term 3.205]

3.23
process variable
chemical or physical attribute within a cleaning, disinfection, packaging, or sterilization process, changes in which can alter its effectiveness

EXAMPLES Time, temperature, pressure, concentration, humidity, wavelength.

[SOURCE: prEN ISO 11139:2017, term 3.214]

3.24
reference measurement point
location of the sensor controlling the operating cycle

[SOURCE: prEN ISO 11139:2017, term 3.230]

3.25
services
supplies from an external source needed for the function of equipment

[SOURCE: prEN ISO 11139:2017, term 3.256]

EXAMPLES Electricity, sterilant, compressed air, drainage.

3.26
stage
<operating cycle> part of an operating cycle with a specified function

EXAMPLES Air removal stage, plateau period, drying stage and final air admission stage.

[SOURCE: prEN ISO 11139:2017, term 3.266]

3.27
sterilant
chemical or combination of chemicals used to generate a sterilizing agent

[SOURCE: prEN ISO 11139:2017, term 3.272]

3.28
sterilant injection
introduction of sterilant into the evacuated chamber until the set operating pressure has been attained or the specified quantity of sterilizing agent has been delivered

[SOURCE: prEN ISO 11139:2017, term 3.273]

3.29
sterile
free from viable microorganisms

[SOURCE: prEN ISO 11139:2017, term 3.275]

Note 1 to entry For “free from viable microorganisms” see EN 556-1.

3.30
sterile barrier system
minimum package that minimizes the risk of ingress of microorganisms and allows aseptic presentation of the sterile product at the point of use

[SOURCE: prEN ISO 11139:2017, term 3.276]

3.31
sterilization
process used to render product free from viable microorganisms

Note 1 to entry In a sterilization process, the nature of microbial inactivation is exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: prEN ISO 11139:2017, term 3.282]

Note 2 to entry For “free from viable microorganisms” see EN 556-1.

3.32
sterilization cycle
predetermined sequence of stages performed in a sterilizer to achieve product free of viable microorganisms

[SOURCE: prEN ISO 11139:2017, term 3.284]

3.33
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

Note 1 to entry This series of actions includes pre-treatment of product (if necessary), exposure under defined conditions to the sterilizing agent and any necessary post treatment. The sterilization process does not include any cleaning, disinfection or packaging operations that precede sterilization.

[SOURCE: prEN ISO 11139:2017, term 3.289]

3.34
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based

[SOURCE: prEN ISO 11139:2017, term 3.291]

3.35
sterilizer
equipment designed to achieve sterilization

[SOURCE: prEN ISO 11139:2017, term 3.292]

3.36
temperature band
range of temperatures expressed as the minimum and the maximum temperatures which prevail throughout the load during the defined period of a cycle

[SOURCE prEN ISO 11139:2017, term 3.298]

3.37
sterilizing agent

physical or chemical entity, or combination of entities, having sufficient microbicidal activity to achieve sterility under defined conditions

[SOURCE: prEN ISO 11139:2017, term 3.293]

3.38
usable chamber volume
defined space within the chamber that is available to accept the load

[SOURCE: prEN ISO 11139:2017, term 3.324]

3.39
validation
confirmation process, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled

[SOURCE: prEN ISO 11139:2017, term 3.319]

3.40
verification
provision of objective evidence, that the specified requirements have been fulfilled

Note 1 to entry The objective evidence needed for a verification can be the result of an inspection or of other forms of determination such as performing alternative calculations or reviewing documents.