SLOVENSKI STANDARD
SIST EN 1422:2014

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Nadomešča:
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Sterilizatorji za uporabo v medicini - Sterilizatorji z etilenoksidom - Zahteve in preskusne metode

Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods

Sterilisatoren für medizinische Zwecke - Ethylenoxid-Sterilisatoren - Anforderungen und Prüfverfahren

Stérilisateurs à usage médical - Stérilisateurs à l'oxyde d'éthylène - Exigences et méthodes d'essai

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11.080.10	Sterilizacijska oprema	Sterilizing equipment

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Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods

Stérilisateurs à usage médical - Stérilisateurs à l'oxyde d'éthylène - Exigences et méthodes d'essai

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Foreword

This document (EN 1422:2014) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, 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of an identical text or by endorsement, at the latest by November 2014 and conflicting national standards shall be withdrawn at the latest by May 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 1422:1997+A1:2009.

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.

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

Annexes A, B, C and D are normative and form part of this European Standard.

Annexes E and ZA are for information only.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN 1422:1997+A1:2009:

— new specification of the scope of the standard, e.g. explicit exclusion of sterilizers which employ the injection of EO or mixtures containing EO directly into packages or into a flexible chamber and removal of different types A and B of EO-sterilizers ;

— normative references have been updated;

— layout of the standard brought in line with the standard for LTSF-sterilization (EN 14180);

— the additional requirements from the machinery directive, introduced by the revision of the medical devices directive 2007/47/EC have been addressed (see revised Annex ZA), i.e. update of technical requirements and Tables ZA.1 and ZA.2;

— requirements have been rephrased to be performance requirements instead of design requirements;

— addition of an environmental checklist;

— Annex B has been thoroughly revised and Annex D has been deleted.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

Ethylene oxide (EO) sterilizers employing EO gas as the sterilant, either as a pure gas or in admixture with other gases, are primarily used for the sterilization of heat labile material or product.

The EO-sterilizer specified in this European standard can be used for medical, dental, pharmaceutical veterinary and industrial or related purposes.

The tests described in this European Standard are reference tests intended for use in demonstrating conformity with the performance requirements specified in this European Standard. They can be used in type tests, works tests, in validation and re-validation tests, 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 European Standard does not cover validation and routine control of EO processes (see prEN ISO 11135:2012). EO is a highly reactive chemical which can present a toxic, flammable or explosive hazard if incorrectly handled (see Annex E).

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 Creutzfeld-Jakob disease.

Planning and design of products complying with 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 E of this standard.

By performing tests concurrently and/or in a logical sequence, the total number of tests carried out and waste arising from such tests, is reduced. As a result the burden on the environment can be reduced (see also Annex E).

1 Scope

This European Standard specifies the requirements and the relevant tests for automatically controlled sterilizers employing ethylene oxide (EO) gas as the sterilant, either as a pure gas or a mixture with other gases, being used for the sterilization of medical devices and their accessories.

This European Standard specifies requirements for ethylene oxide sterilizers (EO-sterilizers) working at super or sub-atmospheric pressure for:

— the performance and design of sterilizers to ensure that the process is capable of sterilizing medical devices;

— the equipment and controls of these sterilizers necessary for the validation and routine control of the sterilization processes.

The test loads described in this European Standard are selected to represent a number of loads for the evaluation of the performance of EO sterilizers for medical devices. However, specific loads may require the use of other test loads.

This European Standard does not specify those tests which are necessary to determine the probability of a processed product being sterile, nor the routine quality control tests required prior to release of sterile product. These topics are addressed in prEN ISO 11135:2012.

This European Standard does not specify requirements for occupational safety associated with the design and operation of EO sterilization facilities.

NOTE 1 For further information on safety, see examples in the Bibliography. National or regional regulations can exist.

This European Standard does not cover sterilizers which employ the injection of EO or mixtures containing EO directly into packages or into a flexible chamber.

NOTE 2 See EN ISO 14937.

This European Standard is not intended as a checklist for suitability of an existing EO sterilizer when assessing compliance with prEN ISO 11135:2012. This standard is not intended to be applied retrospectively.

This European Standard does not cover analytical methods for determining levels of residual EO and/or its reaction products.

NOTE 3 For further information see ISO 10993-7.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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, *Pressure equipment - Part 7: Safety systems for unfired pressure equipment*

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

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

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

EN 13445-5, *Unfired pressure vessels - Part 5: Inspection and testing*

EN 14222, *Stainless steel shell boilers*

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

EN 61010-2-040:2005, *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 61010-2-040:2005)*

EN 61326-1:2006, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements (IEC 61326-1:2005)*

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 10993-7:2008, *Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)*

prEN ISO 11135:2012, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO/DIS 11135:2012)*

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

EN ISO 11138-2, *Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2)*

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

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

3 Terms and definitions

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

3.1
aeration
part of the sterilization process during which ethylene oxide and/or its reaction products desorb from the medical device until predetermined levels are reached

Note 1 to entry: This can be performed within the sterilizer and/or in a separate chamber or room.

[SOURCE: prEN ISO 11135:2012, 3.1]

3.2
air admission stage
stage of the cycle beginning with the attainment of the pre-set pressure on the last evacuation of the flushing stage or sterilant removal stage when filtered air is admitted to allow the chamber pressure to equilibrate with ambient pressure

[SOURCE: ISO/TS 11139:2006, 2.48]

3.3
automatic controller
programmed device that, in response to cycle parameters, operates the sterilizer sequentially through the operating cycle(s)

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

[SOURCE: ISO/TS 11139:2006, 2.3]

3.5
calibration
set of operations that establish, under specified conditions, the relationship between values of a quantity indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values realized by standards

[SOURCE: ISO/TS 11139:2006, 2.4]

3.6
conditioning
treatment of product within the sterilization cycle, but prior to ethylene oxide admission, to attain a predetermined temperature and relative humidity

Note 1 to entry: This part of the sterilization cycle can be carried out either at or above atmospheric pressure or under vacuum.

3.7
controlling
regulating variables to specification

3.8
cycle complete
indication that the operating cycle has been completed according to programme and that the sterilized load is ready for removal from the sterilizer chamber

Note 1 to entry: Upon indication of “cycle complete” a further period of aeration of the processed load can be required.

3.9
ethylene oxide exposure time
the period of the sterilization cycle between the end of EO injection and the beginning of EO removal

3.10
fault
one or more of the process parameters lying outside of its/their specified tolerance(s)

[SOURCE: ISO/TS 11139:2006, 2.19]

3.11
flushing
stage of the sterilization cycle in which the ethylene oxide is removed from the load and free chamber space of the sterilization chamber

Note 1 to entry: Flushing is also known as purging.

3.12
indicating
displaying a value, fault or cycle stage

3.13
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific 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 for medical purposes by means of in vitro examination of specimens derived from the human body,

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

[SOURCE: EN ISO 13485:2012, 3.7]

3.14
monitoring
checking against specifications

3.15
preconditioning
treatment of product, prior to the sterilization cycle, in a room or chamber to attain specified limits for temperature and relative humidity

[SOURCE: prEN ISO 11135:2012, 3.25]

3.16
process challenge device
PCD
item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process

[SOURCE: ISO/TS 11139:2006, 2.33]

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

3.17
process parameter
specified value for a process variable

[SOURCE: ISO/TS 11139:2006, 2.34]

Note 1 to entry: The specification for a sterilization process includes the process parameters and their tolerances.

3.18
process temperature
specified chamber temperature for the sterilization cycle

3.19
process variable
condition within a sterilization process, changes in which alter microbicidal effectiveness

[SOURCE: ISO/TS 11139:2006, 2.35]

EXAMPLES Time, temperature, pressure, concentration, humidity.

3.20
recording
collecting and storing data

Note 1 to entry: Data storing can be realised electronically or by hard copy.

3.21
response time
time required for a 90 % change in sensor output when exposed to a step change in the variable being measured

3.22
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2012, 2.18]

3.23
risk control
process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

[SOURCE: EN ISO 14971:2012, 2.19]

3.24
services
supplies from an external source, needed for the function of equipment

EXAMPLE Electricity, water, compressed air, drainage.

[SOURCE: ISO/TS 11139:2006, 2.41]

3.25
sterile
free from viable microorganisms

[SOURCE: ISO/TS 11139:2006, 2.43]

3.26
sterilizer
apparatus designed to achieve sterilization

[SOURCE: EN 285:2006+A2:2009, 3.35]

3.27
EO sterilization cycle
treatment in a sealed chamber comprising air removal, conditioning (if used), injection of ethylene oxide, exposure to ethylene oxide, removal of ethylene oxide and flushing (if used), and air/inert gas admission

[SOURCE: prEN ISO 11135:2012, 3.48]

Note 1 to entry: EO sterilization cycle does not include aeration (if required).

3.28
sterilization load
product(s) to be, or that has been, sterilized together using a given sterilization process

[SOURCE: ISO/TS 11139:2006, 2.48]

3.29
software validation
confirmation and provision of objective evidence that the requirements for a specific intended use or specification of the software have been fulfilled

Note 1 to entry: In accordance to EN ISO 9000.

3.30
sterilization process
series of actions or operations needed to achieve the specified requirements for sterility

[SOURCE: ISO/TS 11139:2006, 2.49]

Note 1 to entry This series of actions or operations includes pre-treatment (if necessary), exposure to the EO under defined conditions and any necessary post-treatment required for the removal of EO and its by-products to the point where it is safe for the operator to remove the load from the sterilization chamber. It does not include any cleaning, disinfection or packaging operations that precede the sterilization process.

3.31
type test
series of checks and tests for a particular design of sterilizer to demonstrate compliance with the requirements of this European Standard

Note 1 to entry: Additional type tests can be required by the purchaser to show compliance to a specific specification.

3.32
usable chamber volume
defined space within the sterilizer chamber, which is not restricted by fixed or mobile parts and which is available to accept the sterilization load

EXAMPLE The available space on a pallet of defined dimensions.

Note 1 to entry: The maximum load volume is likely to be less than the usable chamber volume as space is required to allow for circulation of sterilant gasses.

[SOURCE: prEN ISO 11135:2012, 3.56]

3.33
verification
confirmation through provision of objective evidence that specified requirements have been fulfilled

[SOURCE: EN 62304:2006, 3.33]

3.34
works test
series of tests performed prior to delivery to demonstrate compliance of equipment with its specification

Note 1 to entry: In accordance with EN ISO 15883-1:2009.

4 Technical requirements

4.1 General

If a pressure vessel according to the Pressure Equipment Directive (PED) is used for the sterilization, the vessel shall comply with EN 13445-3, EN 13445-5 and EN 764-7.

If a shell boiler is used to generate the steam used in the sterilizer, it shall comply with EN 14222.

NOTE 1 See Council Directive concerning pressure equipment (97/23/EEC) [3].

NOTE 2 Sterilizer chambers that run sterilization cycles designed to operate completely below 1,5 bar, do not fall under the Pressure Vessel Directive (PED). Appropriate pressure relief valves can used to ensure over pressurisation does not occur.

NOTE 3 Other European directives can apply. Examples of directives that can apply include, but are not restricted to, the LVD [5], EMC [4], ATEX [2], REACH [10].

4.1.1 Risk control and usability

4.1.1.1 Risk assessment and risk control for sterilizer design and software shall be performed following the procedures and requirements given in EN ISO 14971:2012, Clauses 5, 6 and 7.

4.1.1.2 Risk analysis shall address the specific EO-sterilizer design and features. Measures taken for risk reduction shall consider aspects as user knowledge, experience, training, ergonomics and usability.

NOTE EN ISO 12100 or EN 61508–1 can provide further helpful information.

4.1.2 Materials

4.1.2.1 All materials used for the construction of an EO-sterilizer and instrumentation (for example, door seals, gaskets welds, ancillary items, pipe work, valves and sensors) which can come into contact with EO and other process chemicals (for example water, compressed air and steam) shall be of materials which, under the designed operating conditions:

— are not corroded by EO, its diluent gasses or potential contaminants or steam and/or be subject to metallic corrosion;

— will not react with EO, its diluent gasses or potential contaminants or steam;

— will not promote the polymerization or decomposition of EO;

— will not allow diffusion of EO to an extent which impairs their safe operation.

Due attention should be paid to the effects of mechanical effects and differential expansion when dissimilar metals are used in contact.

NOTE 1 When selecting materials for construction, the material safety data sheet for EO can be referenced.

NOTE 2 The compatibility of materials with ethylene oxide has been addressed in literature (e.g.[6]).

4.1.2.2 The admissible pressure and temperature range (see 9.2) shall be specified when selecting materials for construction.

4.2 Sterilizer chamber

4.2.1 Chamber size

The internal dimensions of the chamber shall be designated by reference to the principle dimensions, measured in millimetres:

a) for cylindrical horizontal or cylindrical vertical chambers:

   — diameter,

   — depth;

b) for rectangular parallelepiped chambers:

   — width,

   — height,

   — depth;

c) for other configurations the chamber shall be specified in analogy to a) or b).

4.2.2 Doors, closures and interlocks of the sterilizer chamber

4.2.2.1 After closing the sterilizer door, it shall be possible to open it before a cycle has been started.