SLOVENSKI STANDARD
SIST EN 14180:2014

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Nadomešča:
SIST EN 14180:2003+A2:2009

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

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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

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Foreword

This document (EN 14180:2014) 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of an identical text or by endorsement, at the latest by November 2014 and conflicting national standards shall be withdrawn at the latest by November 2014.

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 14180:2003+A2:2009.

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(s).

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

The standard is a full technical revision of the previous version. The following amendments have been made in comparison to EN 14180:2003+A2:2009:

— normative references were updated;

— terms risk assessment, risk analysis and software validation were added;

— align biological testing with method from EN ISO 25424;

— requirements for heat isolation were updated;

— safety requirements, mainly as a consequence of compliance with the machinery directive were added;

— requirements and testing for sound power, also including vibration, were updated;

— Annex ZA including Tables ZA1 and ZA2 were updated.

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

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

LTSF sterilizers are primarily used for the sterilization of medical devices in health care facilities, but can 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 [8]. 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 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 Creutzfeld-Jakob Disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents. See also EN ISO 25424:2011, 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 F of this standard.

NOTE Specifications on operator safety are addressed in EN 61010–1, EN 61010–2–040 and are not repeated in this standard. EN 60204–1 can also give valuable guidelines.

1 Scope

This European Standard 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.

This European Standard specifies minimum requirements:

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

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

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 867–5, *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, *Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods*

EN 14222:2003, *Stainless steel shell boilers*

EN 60584–2, *Thermocouples — Part 2: Tolerances*

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 61010-2-040:2005, *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 61326-1:2013, *Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 1: General requirements (IEC 61326-1:2012)*

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 1874-1, *Plastics - Polyamide (PA) moulding and extrusion materials - Part 1: Designation system and basis for specification (ISO 1874-1)*

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 11138-1:2006, *Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2006)*

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

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

3 Terms and definitions

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

3.1
access device
means used to enable access to restricted parts of equipment

Note 1 to entry: This can be a dedicated key, code or tool.

3.2
aeration
part of the sterilization process during which sterilizing agent 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.

3.3
air removal
removal of air from the sterilizer chamber and sterilization load to facilitate sterilant penetration

3.4
automatic controller
device that, in response to cycle parameters, operates the apparatus sequentially through the operating cycle(s)

3.5
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

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

3.6
chamber pre-heating
heating of inner sterilizer chamber surfaces to achieve predetermined temperatures prior to the commencement of a sterilization cycle

3.7
conditioning
treatment of product within the sterilization cycle, but prior to the holding time, to attain a predetermined temperature, humidity and, if applicable, concentration throughout the sterilization load

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

[SOURCE: EN 285:2006+A2:2009, 3.9]

3.9
cycle parameter
specified value for a cycle variable

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

3.10
cycle variable
physical property that influences the efficacy of the operating cycle

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

3.11
desorption
removal of the sterilant from the chamber and the load at the end of the exposure time

3.12
desorption indicator
indicator, intended to determine the amount of sterilant residuals

3.13
double-ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

[SOURCE: EN 285:2006+A2:2009, 3.11]

3.14
exposure time
period between introducing the sterilant into the chamber and the start of the desorption phase

3.15
inoculated carrier
supporting material on or in which a defined number of viable test organisms have been deposited

[SOURCE: EN ISO 11138-1:2006, 3.10]

3.16
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[SOURCE: ISO/TS 11139:2006, 2.22]

3.17
loading door
door in a double ended sterilizer through which the load is put into the sterilizer chamber

[SOURCE: EN 285:2006+A2:2009, 3.17]

Note 1 to entry: See also 3.47 unloading door.

3.18
LTSF-equilibration time
period which elapses between the attainment of the sterilization temperature at the reference measurement point and the attainment of the sterilization temperature at all points within the load

3.19
LTSF - holding time
period for which the temperature at the reference measurement point and all points within the load, and further cycle variables are held within pre-set values and their tolerances

Note 1 to entry: The holding time follows immediately after the equilibration time.

3.20
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]

3.21
microbicidal solution
aqueous solution containing formaldehyde to feed the vaporiser for generating sterilant in the sterilizer

3.22
operating cycle
the automatic sequence of operating stages performed in a sterilizer

3.23
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: ISO/TS 11139:2006, 2.27]

3.24
operator
person operating equipment for its intended purpose

3.25
override
means intended only for maintenance or safety, by which the operating cycle can be interrupted or modified

3.26
post-cycle flushing

stage after “cycle complete” indication, during which the sterilization load is left in the closed chamber and the internal chamber atmosphere is exchanged

3.27
pressure vessel
vessel consisting of the sterilizer chamber, door(s) and other components that form a permanent unit with the sterilizer chamber and that are pressurised by the same pressure

3.28
process challenge device
PCD
item designed to constitute a defined resistance to a 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: ISO/TS 11139:2006, 2.33]

3.29
reference measurement point
point where the temperature sensor used for the operating cycle control is located

3.30
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process

[SOURCE: ISO/TS 11139:2006, 2.40]

3.31
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2012, 2.18]

3.32
risk control
process in which decisions and measures are implemented by which risks are reduced to, or maintaining risks within, specified levels

[SOURCE: EN ISO 14971:2012, 2.19]

3.33
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: EN ISO 9000:2005, modified.3.34.

3.34
sterilant
microbicidal agent composed of steam containing formaldehyde

3.35
sterilant injection
single or repeated stage beginning with the introduction of sterilant into the evacuated sterilizer chamber and ending when the set operating pressure has been attained

3.36

sterile
free from viable microorganisms

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

3.37
sterilization
validated 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: ISO/TS 11139:2006, 2.47]

3.38
sterilizer
equipment designed for the purpose of sterilization

3.39
sterilizer chamber
part of the sterilizer which receives the sterilization load

[SOURCE: EN ISO 17665-1:2006, 3.56]

3.40
sterilization cycle
predetermined sequence of operating stages performed in a sterilizer for the purpose of sterilization and desorption

3.41
sterilization load
product to be, or that has been, sterilized together using a given sterilization process

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

3.42
sterilization process
series of actions or operations 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: ISO/TS 11139:2006, 2.49]

3.43
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based

[SOURCE: EN 285:2006+A2:2009, 3.33]

3.44
sterilization temperature band
temperature range the minimum of which is the sterilization temperature

Note 1 to entry: These temperatures are usually stated in whole degrees Celsius.

3.45
sterilizing agent
physical or chemical entity, or combination of entities having sufficient microbicidal activity to achieve sterility under defined conditions

[SOURCE: ISO/TS 11139:2006, 2.50]

Note 1 to entry: The sterilizing agent is the condensate film, generated by condensation of the sterilant on the surface of the medical devices to be sterilized.

3.46
theoretical sterilant temperature
temperature of the sterilant, calculated from the temperature versus vapour pressure relationship of the sterilant

Note 1 to entry: This value is calculated from the beginning of the exposure time until the beginning of aeration.

3.47
unloading door
door in a double-ended sterilizer through which the sterilization load is removed from the sterilizer chamber after a sterilization cycle

Note 1 to entry: See also 3.18 loading door.

3.48
usable space
specified space inside the sterilizer chamber, which is not restricted by fixed parts and which is available to accept the sterilization load

3.49
validation
documented procedure for obtaining recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[SOURCE: EN ISO 11139:2006, 3.35]

3.50
verification
confirmation through provision of objective evidence that specified requirements have been fulfilled

[SOURCE: EN 62304:2006, 2.55]

3.51
works test
series of tests performed prior to delivery to demonstrate compliance of each piece of equipment with its specification

4 Technical requirements

4.1 Sterilizer chamber

4.1.1 Materials

4.1.1.1 The surfaces of the materials for the pressure vessel (including, for example, welds) that can come into contact with process chemicals shall be of materials which, under the designed operating conditions, are not impaired by these chemicals. They shall not release any substances known to be toxic in such quantities that can create a health or environmental hazard.

NOTE When dissimilar metals are used in contact, this can cause contact corrosion and differential expansion.

4.1.1.2 Materials for sterilizer furniture including load supporting systems shall be selected to avoid corrosion and galvanic attack.

4.1.2 Chamber size

For the usable space the following dimensions shall be specified in millimetres, as applicable:

a) for cylindrical horizontal or cylindrical vertical usable spaces: 000 x 000 in which:

   1) the first three digits give the diameter of the usable space; and

   2) the last three digits give the depth of the usable space;

b) for rectangular parallelepiped usable spaces: 000 x 000 x 000 in which:

   1) the first three digits give the width of the usable space;

   2) the next three digits give the height of the usable space; and

   3) the final three digits give the depth of the usable space;

c) for other configurations the usable space shall be specified in analogy to a) or b);

d) if any dimension exceeds 1000 mm then four digits shall be used, without a decimal point.

4.1.3 Doors and interlocks of the sterilizer chamber

4.1.3.1 Sterilizer chambers shall be provided with one or two doors.

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

4.1.3.3 It shall not be possible to open a sterilizer door(s) during a cycle.

4.1.3.4 In case of an interrupted cycle (e. g. due to a fault), opening of the sterilizer door e. g. to gain access to the load shall require the use of an access device.

4.1.3.5 The design shall allow easy and safe maintenance of the door seal(s) according to the instructions of the manufacturer.

4.1.3.6 For double-ended sterilizers it shall not be possible to open the unloading door until a “cycle complete” indication is obtained.

4.1.3.7 For operating cycles dedicated for test or maintenance purposes only, the “cycle complete” indication shall be different from that of a normal sterilization cycle. For double-ended sterilizers such “cycle complete” indications shall not permit the unloading door to be opened.

4.1.3.8 The control used to start the automatic operating cycle shall be located at the loading side of the sterilizer.

4.1.3.9 Except for maintenance purposes it shall not be possible to open both doors simultaneously on double-ended sterilizers.

4.1.3.10 For double-ended sterilizers both ends of the sterilizer shall be fitted with a device to indicate whether the door at that end can be opened.

4.1.3.11 The indication “cycle complete” shall be cancelled when a door is opened. For double-ended sterilizers the loading door shall remain locked until the unloading door has been opened, closed and locked again.

4.1.4 Heating and insulating the sterilizer chamber

4.1.4.1 Inner sterilizer chamber surfaces shall be heated to achieve pre-set temperatures. Initiation of the sterilization cycle shall not be possible until this condition has been fulfilled.

4.1.4.2 Where hot outer surfaces of the sterilizer chamber can cause a hazard and to reduce heat transmission to the environment, these surfaces shall be isolated, except where this will interfere the intended function of the sterilizer. This applies as well to dedicated steam supply systems, if integral part of the sterilizer.

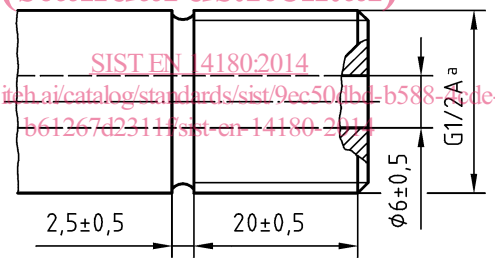
4.1.5 Test connections

4.1.5.1 The sterilizer chamber shall be provided with a test connection, which is used for the connection of a test pressure measuring instrument. This connection shall be at a point of easy access, but not in a pipe for media transport or evacuation, and shall terminate in a pipe thread ISO 228-G1/2A according to EN ISO 228-1. An example is given Figure 1.

The test connection shall be provided with a cap marked PT (Pressure Test) and sealed with a sterilant proof and mechanically resistant O-ring seal or flat seal.

NOTE If national regulations require the calibration of all pressure instruments connected to the pressure vessel, test tees and valve cocks with sealing plugs can be required to permit connection of reference instruments.

Dimensions in millimetres



Key

[a] pipe thread ISO 228-G1/2A

Figure 1 — Example of the connection for test instruments

4.1.5.2 The sterilizer chamber shall be provided with a straight thermometry entry connection. An example is given in Figure 2. This connection shall be at a point of easy access.

The connection shall be provided with a cap marked TT (Temperature Test) and sealed with a sterilant proof and mechanically resistant O-ring seal or flat seal.