SLOVENSKI STANDARD
SIST EN 14180:2003+A2:2009

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Sterilizatorji za uporabo v medicini - Sterilizatorji s paro nizke temperature 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

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This European Standard was approved by CEN on 16 May 2003 and includes Amendment 1 approved by CEN on 12 April 2009 and Amendment 2 approved by CEN on 13 June 2009.

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Foreword

This document (EN 14180:2003+A2:2009) 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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-04-12 and Amendment 2, approved by CEN on 2009-06-13.

This document supersedes ⟦A2⟩ EN 14180:2003+A1:2009 ⟨A2⟩.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟦A1⟩ ⟨A1⟩ and ⟦A2⟩ ⟨A2⟩.

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.

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

Annexes E, F and ZA are for information only.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and 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 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. The sterilizers operate automatically using pre-set cycles.

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

[A2] 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 15424.

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 Encephalophaty 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 15424:2007 1.2.1). [A2]

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 Risk analysis methods, e. g. in EN ISO 14971, pay attention to environmental aspects.

Specifications on operator safety are addressed in EN 61010–1, [A2] EN 61010–2–040 [A2] and are not repeated in this standard. EN 60204–1 may 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

[A1] The following referenced documents are indispensable for the application 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. [A1]

[A2] *deleted text* [A2]

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 materials and systems for medical devices which are to be sterilized — Parts 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods.*

EN 60584–2, *Thermocouples — Part 2: Tolerances (IEC 60584–2:1982 + A1:1989).*

EN 60751, *Industrial platinum resistance thermometer sensors (IEC 60751:1983 + A1:1986).*

EN 61010–1, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 1: General requirements (IEC 61010-1:2001).*

[A2] EN 61010-2-040, *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)* [A2]

EN 61326:1997, *Electrical equipment for measurement, control and laboratory use — EMC requirements (IEC 61326:1997).*

EN ISO 3746, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:1995).*

[A2] EN ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2006)* [A2]

[A2] EN ISO 11138-5, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2006)* [A2]

ISO 228–1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation.*

3 Terms and definitions

[A1] For the purposes of this document, the following terms and definitions apply. [A1]

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

NOTE This may be a dedicated key, code or tool.

3.2
aeration
a part or parts of the sterilization process in which defined conditions are used such that formaldehyde and its reaction products are desorbed from the medical device, and which can be performed within the sterilizer, within a separate room or chamber, or by a combination of the two

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 pre-determined cycle variables, operates the sterilizer sequentially through the required stages of the operating cycle

[A2]

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

[ISO/TS 11139:2006, definition 2.3] A2

3.6
chamber pre-heating
the 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 and humidity throughout the sterilization load

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

[EN 285:1996, definition 3.10]

3.9
cycle parameter
specified value for a cycle variable

3.10
cycle variables
the physical properties that influence the efficacy of the sterilization cycle

NOTE For LTSF-sterilizers, the cycle variables include, but may not be 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
double-ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

[EN 285:1996, definition 3.13]

3.13
equilibration time
period which elapses between the attainment of the sterilization temperature at the reference measuring point and the attainment of the sterilization temperature at all points within the load

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

3.15
holding time
period for which the temperature, the steam pressure and the formaldehyde concentration of the steam are held within pre-set values and their tolerances to achieve the required inactivation efficacy in the sterilizer chamber

NOTE The holding time follows immediately after the equilibration time.

3.16
inoculated carrier
a carrier on which a defined number of test organisms has been deposited

[EN 866-1:1997, definition 3.8]

3.17
installation qualification
IQ
obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[EN ISO 14937:2000, definition 3.9]

3.18
loading door
door in a double-ended sterilizer through which the sterilizer load is put into the sterilizer chamber prior to sterilization

[EN 285:1996, definition 3.21] (See also 3.43 unloading door)

3.19
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

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

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

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

— control of conception,

and which does not achieve its principal 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

[EN ISO 13485:2000, definition 3.1]

3.20
microbicidal solution
aqueous solution containing formaldehyde to feed the vaporiser for generating sterilant in the sterilizer

3.21
operating cycle
the automatic sequence of operating stages performed in a sterilizer

[EN 1422:1997, definition 3.24]

3.22
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[EN ISO 14937:2000, definition 3.12]

3.23
operator
person operating equipment for its intended purpose

3.24
override
means intended only for maintenance or safety, by which the operating cycle can be interrupted or modified

3.25
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

3.26
pressure vessel
a 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

3.27
process challenge device
item designed to simulate product and used to assess the penetration performance of the sterilization cycle

NOTE 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).The indicator should not interfere with the function of the process challenge device.

3.28
production test
series of tests performed to demonstrate compliance of each sterilizer with its type test performance

3.29
reference measuring point
the point where the temperature sensor for the sterilization cycle control is located

3.30
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process [EN ISO 14937:2000, definition 3.20]

3.31
sterilant
microbicidal agent composed of steam containing formaldehyde

3.32
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

3.33
sterile
free from viable micro-organisms

[EN ISO 14937:2000, definition 3.23]

3.34
sterilization
validated process used to render a product free from viable micro-organisms

NOTE In a sterilization process the nature of microbial inactivation is described by an exponential function. Therefore the presence of a viable micro-organism on any individual item can be expressed in terms of probability. This probability may be reduced to a very low number, it can never be reduced to zero.

3.35
sterilizer
apparatus designed to achieve sterilization

[EN 285:1996, 3.36]

3.36
sterilizer chamber
that part of the sterilizer, which receives the sterilizer load

[EN 285:1996, definition 3.37]

3.37
sterilization cycle
predetermined sequence of operating stages performed in a sterilizer for the purpose of sterilization and desorption

3.38
sterilization load
items that are to be, are being or have been sterilized simultaneously in one sterilizer chamber

3.39
sterilization process
series of actions or operations to achieve the specified requirements for sterility and for reduction of sterilant residues to an acceptable level

NOTE This series of actions or operations includes pre-treatment (if necessary), exposure to the sterilizing agent under defined conditions, and any necessary post-treatment. It does not include any necessary operations preceding the sterilization process, such as cleaning, disinfection or packaging.

3.40
sterilization temperature
minimum temperature of the sterilization temperature band on which the evaluation of the sterilization efficacy is based

3.41
sterilization temperature band

temperature tolerance range for the load and the reference measuring point, the minimum of which is the sterilization temperature

3.42
theoretical sterilant temperature
the temperature of the sterilant, calculated from the temperature versus vapour pressure relationship of the sterilant

NOTE This value is calculated from the beginning of the exposure time until the beginning of aeration.

3.43
unloading door
door in a double-ended sterilizer through which the sterilizer load is removed from the sterilizer chamber after a sterilization cycle

[EN 285:1996, definition 3.42] (See also 3.18 loading door)

3.44
usable space
space inside the sterilizer chamber, which is not restricted by fixed parts and which is, according to the manufacturer's specification, available to accept the sterilization load

3.45
validation
documented procedure for obtaining recording and interpreting the results required to establish that a process will consistently yield product complying with predetermined specifications

[EN ISO 14937:2000, definition 3.32]

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 In the selection of materials for pressure parts and their integral attachments, due attention should be paid to the effects of contact corrosion and differential expansion when dissimilar metals are used in contact.

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:

- the first three digits give the diameter of the usable space; and
- the last three digits give the depth of the usable space.

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

- the first three digits give the width of the usable space;
- the next three digits give the height of the usable space; and
- 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 Means shall be provided to allow access to sealing surfaces for cleaning purposes and for replacing the door seal(s).

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 the sterilizer chamber

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.

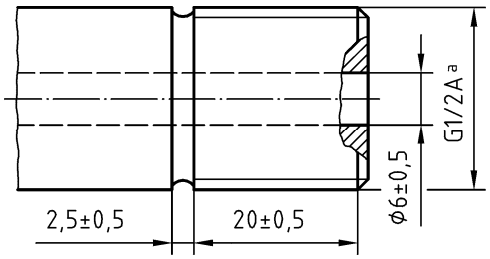
4.1.5 Test connections

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. 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 may be required to permit connection of reference instruments.

Dimensions in millimetres



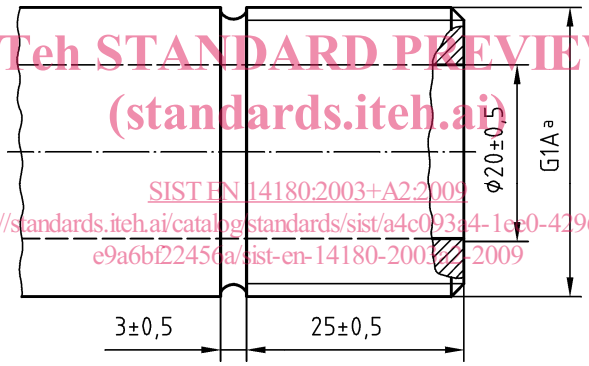
[a]pipe thread ISO 228-G1/2A

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.

Dimensions in millimetres



[a]pipe thread ISO 228-G1A

Figure 2 — Example of thermometry entry connection

4.2 Design and construction

4.2.1 General

A Council Directive on the approximation of the laws of the member states concerning pressure equipment was released on 29 May 1997 (97/23/EC) and corresponding European Standards EN 13445 and EN 14222, may apply.

4.2.2 Pipework and fittings

4.2.2.1 Pipeworks and fittings (including e. g. seals) which may 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 To avoid heat loss or condensation, all pipework carrying media to the sterilizer should be isolated except where this will interfere with the function of the sterilizer.

4.2.2.2 Connections for water and steam supply and drainage shall be provided with means to prevent the ingress of particles which could affect the performance of a sterilizer.

NOTE For connections to potable water supply and draining, national or local regulations may apply.

4.2.2.3 Pipework shall be designed to prevent accumulation of condensate.

4.2.2.4 All control valves in the pipework shall be marked with permanent identification in relation to their functions (see 8.4).

4.2.3 Evacuation system

4.2.3.1 Sterilizers shall be provided with a vacuum system to remove air, water and sterilant. The lowest absolute pressure needed for fulfilling the requirements of clause 6 when tested according to A.3 shall be specified.

NOTE Vacuum systems mostly operate by means of water. Attention should be paid to optimise the use of water in such systems, as there could be a balance between the use of resources and diluting of formaldehyde into concentrations harmless to environment (See also annex F).

4.2.3.2 The sterilizer shall be provided with a means for leaktesting which shall include the sterilizer chamber and all relevant connected pipework and fittings.

At leak testing the chamber and relevant pipework shall be evacuated to or below the lowest process pressure. The pressure rise shall not exceed 0,1 kPa/min over a period of not less than 5 min and not more than 15 min after obtaining the lowest pressure.

4.2.4 Electrical and mechanical safety

4.2.4.1 For general design, EN 61010–1 and [A2] EN 61010–2–040 [A2] shall apply.

NOTE For guidance regarding specific design aspects, EN 60204–1 may apply. The guidance in EN 60204–1 may reduce testing.

[A2]

4.2.4.2 Sterilizers shall comply with EN 61326 regarding electromagnetic compatibility (EMC).

Sterilizers operating either in areas in which medical electrical equipment is intended to be used or in the vicinity of other sensitive equipment shall be regarded as class B equipment as specified in EN 61326.

For immunity, the requirements of EN 61326:2006, Table 2 shall apply.

The selected immunity performance criteria shall ensure that the sterilizer performance as specified in 5.2 will be met during normal operation, when exposed to disturbance phenomena given in EN 61326:2006, Table 2. [A2]

4.2.5 Aeration system

4.2.5.1 When the sterilizer chamber is ventilated during the aeration for the purpose of desorption and to release the vacuum at the end of the process, microbial recontamination of the sterilization load shall be prevented.

4.2.5.2 When a filter is fitted to the sterilizer to prevent microbial recontamination during aeration or pressure equalization, it shall be readily accessible for replacement. The filter shall be capable of retaining at least 99,5 % of particles with a diameter of 0,3 μm at a pressure difference of 1 bar and at maximum airflow.

Means shall be provided between the filter and the sterilisation chamber to prevent fluid flow from the sterilizer chamber into the filter.

4.2.6 Framework and panelling

4.2.6.1 If the sides of the sterilizer need not to be accessible for normal operation, they shall be enclosed with panelling.