



SLOVENSKI STANDARD
SIST EN 285:2006+A1:2008

01-julij-2008

Sterilizacija - Parni sterilizatorji - Veliki sterilizatorji

Sterilization - Steam sterilizers - Large sterilizers

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

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Ta slovenski standard je istoveten z: EN 285:2006+A1:2008

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ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

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English Version

Sterilization - Steam sterilizers - Large sterilizers

Stérilisation - Stérilisateurs à la vapeur d'eau - Grands stérilisateurs

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This European Standard was approved by CEN on 27 April 2006 and includes Amendment 1 approved by CEN on 4 February 2008.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

	Page
Foreword.....	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	6
4 Mechanical components	11
5 Process components	14
6 Instrumentation, indicating and recording devices	15
7 Control systems.....	22
8 Performance requirements	23
9 Sound power	26
10 Rate of pressure change.....	26
11 Safety	27
12 Marking	27
13 Service and local environment.....	27
14 Testing	29
15 A1 Hollow load test.....	31
16 Thermometric tests.....	32
17 Bowie and Dick test.....	36
18 Air leakage test	37
19 Air detector tests	38
20 Load dryness tests	41
21 Sound power test.....	44
22 Steam quality tests	45
23 Dynamic sterilizer chamber pressure test	55
24 Test apparatus, equipment and material.....	56
25 Documentation to be supplied by the manufacturer	63
26 Information to be supplied by the manufacturer.....	64
Annex A (informative) Environmental aspects.....	67
Annex B (informative) Steam supply; suggested maximum values of contaminants in feed water and condensate	72
Annex C (informative) Recommended materials	73
Annex D (informative) Temperature and time tolerances during the small load thermometric test	76
Annex E (informative) Guidance for installation and operational qualification tests to be included in the instructions for use supplied with a sterilizer.....	77
Annex F (informative) Criteria for identifying sterilizers as the same type.....	79

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	80
Bibliography	81

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SIST EN 285:2006+A1:2008
<https://standards.iteh.ai/catalog/standards/sist/68a6b969-bfa1-4c2d-9610-38b78b286c79/sist-en-285-2006a1-2008>

Foreword

This document (EN 285:2006+A1:2008) 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 September 2008 and conflicting national standards shall be withdrawn at the latest by November 2008.

This document includes Amendment 1, approved by CEN on 2008-02-04.

This document supersedes A1 EN 285:2006 A1.

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

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 does not specify requirements for the validation and routine control of sterilization by moist heat. A European Standard specifying requirements for the validation and routine control of sterilization by moist heat was prepared by CEN/TC 204 "Sterilization of medical devices" see EN 554 (currently under revision, see prEN ISO 17665).

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. However, some national regulations require the use of modified steam processes as part of a general prion decontamination programme.

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.

1 Scope

1.1 This European Standard specifies requirements and the relevant tests for large steam sterilizers primarily used in health care for the sterilization of medical devices and their accessories contained in one or more sterilization modules. The test loads described in this European Standard are selected to represent the majority of loads (i.e. wrapped goods consisting of metal, rubber and porous materials) for the evaluation of general purpose steam sterilizer for medical devices. However, specific loads (e.g. heavy metal objects or long and/or narrow lumen) will require the use of other test loads.

Large steam sterilizers can also be used during the commercial production of medical devices.

1.2 This European Standard is not applicable to steam sterilizers designed to process a size of load less than one sterilization module or having a chamber volume less than 60 l.

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

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

1.4 Planning and design of products applying to this European Standard should consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex A.

NOTE Additional aspects of environmental impact are addressed in EN ISO 14971.

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2 Normative references

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.

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EN 764-1:2004, *Pressure equipment — Part 1: Terminology — Pressure, temperature, volume, nominal size*

A1 *deleted text* A1

EN 867-3, *Non-biological systems for use in sterilizers — Part 3: Specification for Class B indicators for use in the Bowie and Dick test*

A1 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* A1

EN 868-5, *Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods*

EN 1822 (all parts), *High efficiency air filters (HEPA and ULPA)*

EN 10088-1, *Stainless steels — Part 1: List of stainless steels*

EN 10088-3, *Stainless steels — Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resistant steels for general purposes*

EN 12953 (all parts), *Shell boilers*

EN 13445 (all parts), *Unfired pressure vessels*

EN 14222, *Stainless steel shell boilers*

EN 60584-2:1993, *Thermocouples — Part 2: tolerances (IEC 60584-2:1982 + A1:1989)*

EN 285:2006+A1:2008 (E)

EN 60751:1995, *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)*

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)*

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

EN 61672-1:2003, *Electroacoustics — Sound level meters — Part 1: Specifications (IEC 61672-1:2002)*

EN 61672-2:2003, *Electroacoustics — Sound level meters — Part 2: Pattern evaluation tests (IEC 61672-2:2003)*

EN ISO 3746:1995, *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)*

EN ISO 4017, *Hexagon head screws — Product grades A and B (ISO 4017:1999)*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 764-1:2004 and the following apply.

NOTE Other definitions relevant to validation are given in EN 554.

3.1

access device

means used to permit access to restricted parts of the equipment

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

3.2

air removal

removal of air from the sterilizer chamber and sterilizer load to facilitate steam penetration

3.3

automatic controller

device that, in response to pre-determined cycle variables, operates the sterilizer sequentially through the required stages of the cycle(s)

3.4

biological indicator

microbiological test system providing a defined resistance to a specified sterilization process

[ISO/TS 11139:2001, definition 2.4]

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

[IVM:1994, definition 6.11]

3.6**chamber depth**

depth of the sterilizer chamber which is available for the sterilizer load

3.7**chamber height**

height of the sterilizer chamber which is available for the sterilizer load

3.8**chamber width**

width of the sterilizer chamber which is available for the sterilizer load

3.9**cycle complete**

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

3.10**door**

lid or similar device provided as a means of closing and sealing the sterilizer chamber

3.11**double ended sterilizer**

sterilizer in which there is a door at each end of the sterilizer chamber

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A1 3.12**endpoint**

point of the observed change as defined by the manufacturer occurring after the indicator has been exposed to specified stated values

[EN ISO 11140-1:2005] **A1**

3.13**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

3.14**holding time**

period for which the temperatures at the reference measurement point and at all points within the load are continuously within the sterilization temperature band

NOTE The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

3.15**inoculated carrier**

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

[EN 866-1:1997, definition 3.8]

3.16
installation qualification
IQ

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

[ISO/TS 11139:2001, definition 2.20]

3.17
loading door

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

3.18
medical device

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,

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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

[EN ISO 13485:2003, definition 3.7]

3.19
non-condensable gas

air and other gas which will not condense under the conditions of steam sterilization

3.20
operating cycle

sequence of operating stages which is performed automatically by a sterilizer

3.21
operational qualification
OQ

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

[ISO/TS 11139:2001, definition 2.24]

3.22
operator

person operating equipment for its intended purpose

3.23**plateau period**

equilibration time plus the holding time

3.24**pressure vessel**

vessel comprising the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent connection with the sterilizer chamber

A₁ 3.25**process challenge device****PCD**

item designed to constitute a defined resistance to a sterilization process and used to assess performance of the process ^{A₁}

3.26**reference measurement point**

point where the temperature sensor for the sterilization cycle control is located

3.27**reference standard**

standard, generally having the highest metrological quality available at a given location or in a given organization, from which measurements made there are derived

[IVM:1994, definition 6.6]

3.28**saturated steam**

water vapour in a state of equilibrium between condensation and evaporation

[ISO 13683:1997, definition 3.18]

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3.29**sterile**

condition of a medical device that is free from viable microorganisms

[EN 556-1:2001, definition 3.4]

3.30**sterilization**

validated process used to render a product free from viable microorganisms

[ISO/TS 11139:2001, definition 2.42]

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

3.31**sterilization cycle**

operating cycle performed by a sterilizer for the purpose of sterilization

3.32**sterilization module**

rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)

3.33**sterilization temperature**

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

3.34

sterilization temperature band

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

NOTE These temperatures are usually stated in whole degrees Celsius.

3.35

sterilizer

apparatus designed to achieve sterilization

3.36

sterilizer chamber

part of the sterilizer which receives the sterilizer load

[EN 554:1994, definition 3.27]

3.37

sterilizer load

items that are to be sterilized simultaneously in the same sterilizer chamber

3.38

superheated steam

water vapour whose temperature is higher than the boiling point of water at the corresponding pressure

3.39

test organism

microorganisms used for the manufacture of inoculated carriers

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[EN 866-1:1997, definition 3.16]

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3.40

type test

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

3.41

unloading door

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

3.42

usable space

space inside the sterilizer chamber which is not restricted by fixed parts and which is available to accept the sterilizer load

3.43

works test

series of tests performed at the manufacturer's works to demonstrate that each sterilizer will comply with its specification

4 Mechanical components

4.1 Dimensions

The usable space within the sterilizer chamber shall accommodate one or more sterilization modules.

4.2 Materials

Materials in contact with steam shall:

- resist attack from steam and condensate;
- not cause deterioration of the quality of the steam;
- not release any substances known to be toxic in such quantities that could create a health or environmental hazard.

NOTE 1 Guidance on steam contaminants is given in Table B.2.

NOTE 2 Because of the different types of sterilizers and the large number of uses, it is not possible to specify detailed requirements for materials for specific applications. The purchaser should provide the manufacturer with information about the goods to be sterilized.

NOTE 3 Advice on the various combinations of materials is given in Annex C. However, for some applications, a combination of materials selected from more than one group may be appropriate.

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4.3 Pressure vessel

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4.3.1 General <https://standards.iteh.ai/catalog/standards/sist/68a6b969-bfa1-4c2d-9610-38b78b286c79/sist-en-285-2006a1-2008>

4.3.1.1 The pressure vessel shall comply with EN 13445.

4.3.1.2 The door seal shall be a replaceable component.

It shall be possible to inspect and clean the surface of the door seal which comes into contact with the sealing faces without the need to dismantle the door assembly.

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

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

4.3.2 Double ended sterilizers

4.3.2.1 Except for maintenance purposes it shall not be possible for more than one door to be open at one time.

4.3.2.2 It shall not be possible to open the unloading door until a cycle complete indication is obtained.

4.3.2.3 It shall not be possible to open the unloading door if a Bowie and Dick cycle or an air leakage test has been carried out (see 7.1.14 and 7.1.15).

4.3.2.4 The control used to start the sterilization cycle shall be located at the loading side of the sterilizer.

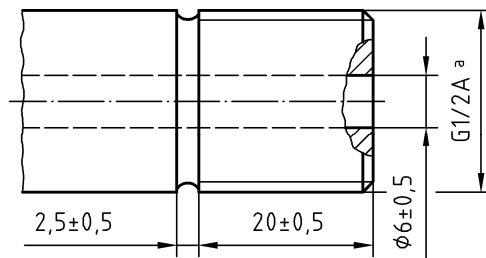
4.3.3 Test connections

4.3.3.1 The connections as required by 4.3.3.2 and 4.3.3.3 shall be provided.

NOTE The test connection for pressure test and temperature test as shown in Figure 1 and Figure 2 may be provided as a combined detachable adapter.

4.3.3.2 A test connection in accordance with Figure 1 shall be fitted to the sterilizer chamber or in a pipe which is in direct connection with the sterilizer chamber providing it causes no adverse effect on the measurement of the pressure in the sterilizer chamber. The test connection which is used for the connection of a test instrument shall be provided with a cap, marked PT (pressure test) and sealed with either an O-ring-seal or a flat seal.

Dimensions in millimetres



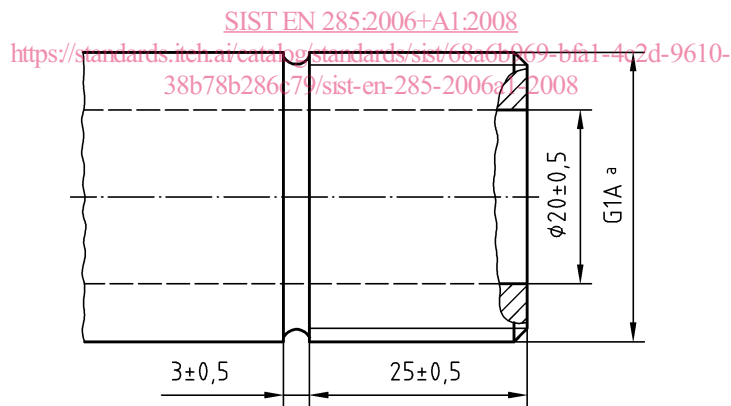
Key

^a Pipe thread EN ISO 228-G 1/2 A

Figure 1 — Connection for test instrument

4.3.3.3 A straight connecting sleeve, in accordance with Figure 2, shall be provided at a point of easy access in order to pass flexible cords to the temperature sensors.

Dimensions in millimetres



Key

^a Pipe thread EN ISO 228-G 1 A

Figure 2 — Connection sleeve for thermoelements

The connecting sleeve with its O-ring-seal or flat seal shall be closed with a cap, and a temperature proof and mechanically resistant soft packing. The cap shall be marked with the letters TT (temperature test).

4.3.3.4 Test tee(s) and valve cock(s) with sealing plug(s) shall be fitted to permit connection of reference instruments for the calibration of all pressure instruments, connected to the sterilizer chamber and jacket (see 6.1.2 and 6.1.4).

4.3.4 Insulating material

Except where insulation would interfere with the function and operation of the sterilizer, external surfaces of the pressure vessel shall be insulated to reduce heat transmission to the environment [see also 26.2 g) and h)].

4.4 Framework and panelling

4.4.1 Where the sides of the sterilizer are visible from the operator area, they shall be enclosed with panelling. The manufacturer shall provide instructions for the cleaning of the panelling.

NOTE The panelling should have a corrosion-resistant finish to the cleaning agents specified by the manufacturer.

4.4.2 The panelling of the sterilizer shall allow access for maintenance work. Such panelling shall be demountable or the dimensions of any personal access shall be not less than 500 mm wide and not less than 1 500 mm high, and the access shall not be obstructed.

NOTE 1 If the pressure equipment is housed in a frame, this frame should not promote corrosion of the equipment.

NOTE 2 The access for maintenance should be positioned so that it will not compromise the safety of either the product or persons.

NOTE 3 Requirements for access are specified in EN 61010-2-040.

4.4.3 The panelling shall be designed to provide a continuous contact with the surfaces of the building in which it is installed when these surfaces are within the tolerances given in Tables 1 and 2.

Sterilizers designed for incorporation into existing buildings, or purpose built rooms shall provide a continuous joint with adjacent surfaces when these are within the limits given in Tables 1 and 2.

Table 1 — Tolerances for the aperture into which the sterilizer is installed

Dimension m	Tolerance mm	
	Horizontal plane	Vertical plane
up to 3	± 12	± 16
above 3 to 6	± 16	± 16
above 6 to 15	± 24	± 20
above 15 to 30	± 24	± 20
above 30	± 30	± 30