SLOVENSKI STANDARD
SIST EN 285:2000

01-januar-2000

Sterilizacija - Parni sterilizatorji - Veliki sterilizatorji

Sterilization - Steam sterilizers - Large sterilizers

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

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

Ta slovenski standard je istoveten z: **EN 285:1996**

ICS:

11.080.10 Sterilizacijska oprema Sterilizing equipment

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Descriptors: sterilization, medical equipment, sterilizers, water vapor, equipment specifications, locking devices, doors, fittings, measuring instruments, indicating instruments, specifications

English version

Sterilization - Steam sterilizers - Large sterilizers

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

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Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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Contents

Foreword

This European Standard has been prepared by Technical Committe 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of an identical text or by endorsement, at the latest by April 1997, and conflicting national standards shall be withdrawn at the latest by April 1997.

This European Standard 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 standard.

This European Standard specifies requirements and the relevant tests for large steam sterilizers. Specifications of requirements and tests for small steam sterilizers as well as for sterilizers using other sterilants than steam are in preparation by CEN/TC 102.

This European Standard 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 "Sterilization of medical devices - Validation and routine control of sterilization by moist heat".

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the 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 one or more sterilization modules for wrapped goods (instruments etc. and porous loads).

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

NOTE: Sterilizers conforming to this standard can offer a single automatic sterilization cycle or a number of selectable automatic sterilization cycles, e.g. with different operating temperatures (see 28.3b).

1.2 This European Standard is not applicable to small steam sterilizers nor to steam sterilizers used for the sterilization of pharmaceutical products in containers.

NOTE: The use of sterilizers for unwrapped instruments and utensils for immediate use in aseptic areas and for fluid-sterilizers will be the subject of a separate standard.

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 systems (see EN ISO 9001, EN ISO 9002, EN ISO 9004-1 and EN 46001 and EN 46002).

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references, the latest edition of the publication referred to applies.

prEN 866-1	Biological systems for testing sterilizers - Part 1: General requirements
prEN 866-3	Biological systems for testing sterilizers - Part 3: Particular systems for use in steam sterilizers
prEN 867-3	Non-biological systems for use in sterilizers - Part 3: Specification for class B indicators for use in the Bowie and Dick test
prEN 868-5	Packaging materials for sterilization of wrapped goods - Part 5: Heat sealable pouches and reel material of paper and plastic construction - Requirements and tests

EN 10088-1	Stainless steels - Part 1: List of stainless steels
EN 10088-2	Stainless steels - Part 2: Technical delivery conditions for sheet/plate and strip for general purposes
EN 10088-3	Stainless steels - Part 3: Technical delivery conditions for semi-finished products, bars, rods and sections for general purposes
EN 50081-1	Electromagnetic compatibility - Generic emmission standard - Part 1: Residential, commercial and light industry
EN 50081-2	Electromagnetic compatibility - Generic emmission standard - Part 2: Industrial environment
EN 50082-1	Electromagnetic compatibility - Generic immunity standard - Part 1: Residential, commercial and light industry
EN 50082-2	Electromagnetic compatibility - Generic immunity standard - Part 2: Industrial environment
EN 60204-1 : 1992	Safety of machinery - Electrical equipment of machines - Part 1: General requirements (IEC 204-1 : 1992, modified)
EN 60584-2 : 1993	Thermocouples - Part 2: Tolerances (IEC 584-2 : 1982 + A1 : 1989)
EN 60651:1994	Sound level meters (IEC 651:1979 + A1:1993)
EN 60751 : 1995	Industrial platinum resistance thermometer sensors (IEC 751 : 1983 + A1 : 1986)
EN 60804 : 1994	Integrating - averaging sound level meters (IEC 804:1985 + A1:1989)
EN 61010-1	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements (IEC 1010-1 : 1990 +A1 : 1992, modified)
IEC 38	IEC Standard voltages
EN 61010-2-041	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-041: Particular requirements for autoclaves using steam for the treatment of medical materials, and for laboratory processes (IEC 1010-2-041:1996)
ISO 228-1	Pipe threads where pressure-tight joints are not made on the threads - Part 1: Dimensions, tolerances and designation
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)
ISO 4017	Hexagon head screws - Product grades A and B

3 Definitions

For the purposes of this standard the definitions of EN 764 apply together with the following.

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

3.1 active drain: Drain which is situated at the lowest part of the sterilizer chamber to control the discharge of air/non-condensable gases or air and condensate from the sterilizer chamber.

3.2 air removal: Removal of air from the sterilizer chamber and sterilizer load sufficient 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: An inoculated carrier contained within its primary pack ready for use [prEN 866-1].

3.5 calibration: The 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.

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 chamber temperature: Lowest temperature prevailing in the sterilizer chamber [EN 554].

3.10 cycle complete: Indication that the sterilization cycle has been satisfactorily completed and that the sterilized load is ready for removal from the sterilizer chamber.

3.11 dedicated steam supply: Supply of steam produced for a sterilizer, or group of sterilizers, by a dedicated generator.

3.12 door: Lid or similar device provided as a means of closing and sealing the sterilizer chamber.

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

3.14 dry saturated steam: Steam with a temperature and pressure corresponding to the vaporization curve of water.

NOTE: This is an ideal condition which can deviate towards either superheated steam or to wet steam. This deviation is quantified by the determination of the Dryness Value.

3.15 equilibration time: Period which elapses between the attainment of the sterilization temperature in the sterilizer chamber and the attainment of the sterilization temperature at all points within the load [EN 554].

3.16 fail safe: Attribute of sterilizer design, component or its associated services that minimizes a possible safety hazard.

3.17 fault: Recognition by the automatic controller that the pre-set cycle variables for the sterilization cycle have not been attained.

3.18 holding time: Period for which the temperature of all points within the sterilizer is held 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.

3.19 inoculated carrier: A carrier on which a defined number of test organisms has been deposited [prEN 866-1].

3.20 installation test: Series of checks and tests performed after installation of the sterilizer in the place of use [EN 554].

3.21 loading door: Door in a double ended sterilizer through which the sterilizer load is put into the sterilizer chamber prior to sterilization.

3.22 medical device: The definition given in EN 46001 applies.

3.23 non-condensable gas: Air and other gas which will not condense under the conditions of steam sterilization.

3.24 plateau period: Equilibration time plus the holding time.

3.25 pressure vessel: A vessel describing the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent connection with the sterilizer chamber.

3.26 reference measurement point: Reference point for which documented evidence is available to demonstrate that it has a known relationship to the temperature of the coolest part of the sterilizer chamber.

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.

3.28 safety hazard: Potentially detrimental effect on persons or the surroundings arising directly from either the sterilizer or its load.

3.29 small steam sterilizers: Steam sterilizer which is unable to accommodate a sterilization module.

3.30 sterile: Condition of a medical device that is free from viable microorganisms [EN 556].

3.31 sterilization: Process undertaken to render a sterilizer load sterile.

3.32 sterilization cycle: Automatic sequence of operating stages performed in a sterilizer for the purpose of sterilization [EN 554].

3.33 sterilization module: Rectangular parallelepiped of the dimensions 300 mm x 300 mm x 600 mm used for the purposes of sterilization.

3.34 **sterilization temperature:** Minimum temperature of the sterilization temperature band [EN 554].

3.35 **sterilization temperature band:** Range of temperatures, expressed as the sterilization temperature and the maximum allowable temperature which may prevail throughout the load during the holding time [EN 554].

NOTE: These temperatures are usually stated in whole degrees Celsius.

3.36 **sterilizer:** Apparatus designed to achieve sterilization.

3.37 **sterilizer chamber:** That part of the sterilizer which receives the sterilizer load [EN 554].

3.38 **sterilizer load:** Goods that are to be sterilized simultaneously in the same sterilizer chamber [EN 554].

3.39 **superheated steam:** Steam whose temperature, at any given pressure, is higher than that indicated by the vaporization curve of water.

3.40 **test organism:** Micro-organisms used for the manufacture of inoculated carriers [prEN 866-1].

3.41 **type test:** Series of tests to establish the working data for a sterilizer type.

3.42 **unloading door:** Door in a double ended sterilizer through which the sterilized load is removed from the sterilizer chamber after a sterilization cycle.

3.43 **usable space:** Space inside the sterilizer chamber which is not restricted by fixed parts and which is consequently available to accept the sterilizer load.

NOTE: The usable space is expressed in terms of chamber height, chamber width and chamber depth.

3.44 **works test:** Series of tests performed at the manufacturer's works to demonstrate compliance of each sterilizer 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;

  NOTE 1: Guidance is given in Annex B.

- not release any substances known to be toxic in such quantities that could create a health hazard.

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 A.

4.3 Pressure equipment

4.3.1 General

4.3.1.1 A Council Directive on the approximation of the laws of the member states concerning pressure equipment (see 93/C246/01) and corresponding European Standards are in preparation (CEN/TC 54 and CEN/TC 269). Until European Standards on pressure equipment are published, the pressure equipment should comply with national regulations and standards applying in the country of intended use.

4.3.1.2 Sterilizers shall be provided with one or two doors.

4.3.1.3 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.

4.3.1.4 After closing the sterilizer door, it shall be possible to open it without having first to initiate a sterilization cycle.

4.3.1.5 Except in the case of a fault it shall not be possible to open a sterilizer door(s) during a sterilization 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.

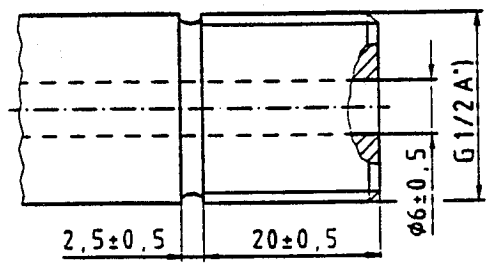
4.3.2.3.It shall not be possible to open the unloading door if a Bowie and Dick test has been carried out.

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 If the sterilization cycle includes a vacuum stage, 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 (excluding vacuum line). The test connection which is used for the connection of a test instrument shall be provided with a standard cap, marked VT (vacuum test) and sealed with either an O-ring-seal or a flat seal.

Dimensions in millimetres

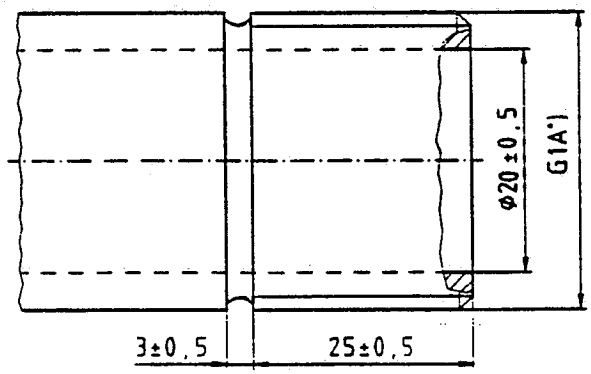


* Pipe thread ISO 228-G 1/2 A

Figure 1: Connection for test instrument

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

Dimensions in millimetres



* Pipe thread 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 standard cap, and a temperature proof and mechanically resistant soft packing. The cap shall be marked with the letters TT (temperature test).

4.3.3.3 Test tees and valve cocks with sealing plugs 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 shall be insulated to minimize heat transmission to the environment such that the temperature of the outer surface of the insulating material does not exceed 55 °C when tested in an environmental temperature of (23 ± 2) °C.

4.4 Framework and panelling

4.4.1 Where the sides of the sterilizer are visible from the user 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 (for example, by the use of a special key, code or tool). Such panelling shall be demountable or the dimensions of any personal access shall be not less than 500 mm wide and not less than 1500 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.

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 tolerances given in tables 1 and 2.

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

Dimension in m	Tolerance in 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

Table 2: Tolerances for vertical and horizontal flatness

Distance between checkpoints in m	Tolerance in mm	
	Finished surfaces of walls and ceilings	Finished floor (bearing surface)
0,1	3	2
1	5	4
4	10	10
10	20	12
15	25	15

5 Process components

5.1 Pipework and fittings

5.1.1 Pipe joints and fittings shall be both pressure-tight and vacuum-tight.

5.1.2 Except where this will interfere with the function of the sterilizer the pipework for steam or water at a temperature greater than 60 °C shall be thermally insulated to minimize heat transmission to the environment. The temperature of the outer surface of insulation material shall not exceed 55 °C when tested in an environmental temperature of (23 ± 2) °C (see 4.3.4).

NOTE: To minimize the formation of condensation cold water pipework should be insulated.

5.1.3 At least one strainer shall be fitted on each service supply line upstream of the first valve on the sterilizer for that service. The size of the strainer selected shall prevent particles passing which would affect the correct operation of the valve.

5.1.4 All control valves in the pipework shall be marked with permanent identification in relation to their functions (see 12.3).

NOTE: Reference numbers or written descriptions can be used.

5.2 Generator for dedicated steam supply and for sterilizers where the steam is generated in the sterilizer chamber

5.2.1 A Council Directive on the approximation of the laws of the member states concerning pressure equipment (see 93/C246/01) and corresponding European Standards are in preparation (CEN/TC 54 and CEN/TC 269). Until European Standards on pressure equipment are published, the pressure equipment should comply with national regulations and standards applying in the country of intended use.

5.2.2 The feed water inlet shall be designed to prevent back-syphoning into the feed water system.

NOTE: This will normally require the use of a break tank which should be made from material resistant to water at 100 °C.

5.2.3 The power requirements and the capacity of the steam generator shall be sufficient to ensure that the steam demand specified for the sterilizer can be met.

5.2.4 The manufacturer shall specify the quality of feedwater required. In particular, the maximum hardness value, the range of pH and the conductivity shall be specified (see 28.2 and table B.1).

5.3 Air filter

5.3.1 Where the sterilization cycle requires the admission of air into the sterilizer chamber direct from the atmosphere, the air shall be admitted through a filter.