SLOVENSKI STANDARD
SIST EN 13060:2005

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Mali parni sterilizatorji

Small steam sterilizers

Dampf-Klein-Sterilisatoren

Petits stérilisateurs a la vapeur d'eau

Ta slovenski standard je istoveten z: **EN 13060:2004**

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11.080.10	Sterilizacijska oprema	Sterilizing equipment

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Small steam sterilizers

Petits stérilisateurs à la vapeur d'eau

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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Management Centre: rue de Stassart, 36 B-1050 Brussels

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Contents

Foreword

This document (EN 13060:2004) 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of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

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 annexes A, B, C, D, E and F are informative.

This document includes a Bibliography.

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Introduction

Small steam sterilizers are widely used for medical purposes, e.g. in general medical practices, dentistry, facilities for personal hygiene and beauty care and also veterinary practices. They are also used for materials and equipment, which are likely to come into contact with blood or body fluids, e.g. implements used by beauty therapists, tattooists, body piercers and hairdressers. The very specific sterilizer loads used within these fields of application call for different performance requirements for the sterilization cycles and different corresponding test methods.

This European Standard specifies the general requirements for small steam sterilizers and test methods for specified sterilizer loads according to Table 1. These loads include unwrapped solid products, full porous load, small porous load, small porous items, hollow loads A, hollow loads B, single wrapped products and double wrapped products. The performance tests specified in this standard can also be used by device manufacturers to specify the appropriate performance for decontamination processes according to the requirements for information to be given by medical device manufacturers according to EN ISO 17664:2004. This will enable users to identify the specific sterilizer performance required to safely process their devices.

Table 1 — Types of sterilization cycles

Type	Description of intended use
B	The sterilization of all wrapped or non-wrapped, solid, hollow load products type A and porous products as represented by the test loads in this standard.
N	The sterilization of non wrapped solid products.
S	The sterilization of products as specified by the manufacturer of the sterilizer including non wrapped solid products and at least one of the following: porous products, small porous items, hollow load products type A, hollow load products B, single wrapped products, multiple-layer wrapped products.
NOTE 1 The description identifies ranges of products and test loads. NOTE 2 Non wrapped sterilized instruments are intended either for immediate use or for non sterile storage, transport and application (e.g. to prevent cross infection).	

It is essential that the sterilizer and associated equipment is used only for the sterilization of the type of products for which it is designed. The choice of sterilizer, sterilization cycle or quality of services provided can be inappropriate for a particular load. Therefore the suitability of a sterilization procedure for a particular product needs to be verified by validation.

1 Scope

This European Standard specifies the performance requirements and test methods for small steam sterilizers and sterilization cycles which are used for medical purposes or for materials that are likely to come into contact with blood or body fluids.

This European Standard applies to automatically controlled small steam sterilizers that generate steam using electrical heaters or use steam that is generated by a system external to the sterilizer.

This European Standard applies to small steam sterilizers used primarily for the sterilization of medical devices and unable to accommodate a sterilization module (300 mm × 300 mm × 600 mm) and with a chamber volume not exceeding 60 litres.

This European Standard does not apply to small steam sterilizers that are used to sterilize liquids or pharmaceutical products.

This European Standard does not specify safety requirements related to risks associated with the zone in which the sterilizer is used (e.g. flammable gases).

This European Standard does not specify requirements for the validation and routine control of sterilization by moist heat.

NOTE Requirements for the validation and routine control of sterilization by moist heat are given in EN 554, which may also be applied for small steam sterilizers.

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 (including amendments).

EN 285:1996, *Sterilization — Steam sterilizers — Large sterilizers.*[1]

EN 475*, Medical devices — Electrically-generated alarm signals.*

EN 866-3*, Biological systems for testing sterilizers and sterilization processes — Part 3: Particular systems for use in moist heat sterilizers.*

EN 867-1:1997, *Non-biological systems for use in sterilizers — Part 1: General requirements.*[2]

EN 867-5:2001, *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 *(all parts)*, *Packaging materials and systems for medical devices which are to be sterilized.* [3]

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

EN 60529*, Degrees of protection provided by enclosures (IP code) (IEC 60529:1989).*

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1 Currently under revision by CEN/TC 102.

2 EN 867-1 is currently under revision by ISO/TC 198 and CEN/TC 102 (Vienna Agreement).

3 EN 868-1 is currently under revision by ISO/TC 198 and CEN/TC 102 (Vienna Agreement).

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

EN 61010-2-041, *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 61010-2-041:1996).*[4]

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

EN ISO 228-1, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation (ISO 228-1:2000).*

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

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

EN ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves (ISO 4126-1:2004).*

EN ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003).*

EN ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2000).*

3 Terms and definitions

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

NOTE Other definitions relevant to steam sterilization and its validation are given in EN 285 and EN 554.

3.1
absolute pressure
pressure for which the zero value is associated with absolute vacuum

[EN 764-1:2004, definition 4.5]

3.2
active drain of small steam sterilizers
drain through which fluids present in the chamber are discharged during the process

3.3
air removal
removal of air from the sterilizer chamber and sterilizer load sufficient to facilitate steam penetration

[EN 285:1996, definition 3.2]

3.4
automatic controller
device that, in response to pre-determined cycle variables, operates the sterilizer sequentially through the required stages of the cycle(s)

[EN 285:1996, definition 3.3]

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4 Currently under revision by IEC/TC 66/WG 7.

3.5
biological indicator
inoculated carrier contained within its primary pack ready for use

[EN 866-1:1997, definition 3.1]

3.6
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 realised by standards

[VIM:1993, definition 6.11]

3.7
chamber temperature
lowest temperature prevailing in the sterilizer chamber

[EN 554:1994, definition 3.3]

3.8
chemical indicator
chemical indicator system in the form in which it is intended to be used

3.9
chemical indicator system
combination of the chemical indicator reagent and its substrate

3.10
closed door
door which is in the position required for it to be locked

3.11
cycle complete indication
indication that the sterilization cycle has been satisfactorily completed as specified and that the sterilized load is ready for removal from the sterilizer chamber

3.12
cycle parameters
specified physical properties, for example time, temperature and pressure, that influence the efficacy of the sterilization process

3.13
defined end-point
visible change occurring after exposure to the specified variable(s) at a level equal to or greater than that specified for the indicator

[EN 867-1:1997, definition 3.2]

3.14
door
lid or a similar device provided as a means of closing and sealing the sterilizer chamber

[EN 285:1996, definition 3.12]

3.15
double ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

[EN 285:1996, definition 3.13]

3.16
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 554:1994, definition 3.5]

NOTE The sterilizer chamber temperature is usually called chamber temperature.

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

[EN 285:1996, definition 3.17]

3.18
holding time of small steam sterilizers
period for which the temperature of all points within the usable space considering the temperature measurement reference position 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
hollow load A

single ended open space where the ratio of length to diameter of the cavity is greater than or equal to 1 and less than/or equal to 750 ($1 \leq L/D \leq 750$) and where the length of the cavity is not greater than 1 500 mm ($L \leq 1\,500$ mm) or double ended open space where the ratio of length to diameter of the cavity is greater than/or equal to 2 and less than or equal to 1 500 ($2 \leq L/D \leq 1\,500$) and where the length of the cavity is not greater than 3 000 mm ($L \leq 3\,000$ mm) and which is not hollow load B

NOTE See annex A.

3.20
hollow load B
single ended open space where the ratio of length to diameter of the cavity is greater than or equal to 1 and less than/or equal to 5 ($1 \leq L/D \leq 5$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm) or double ended open space where the ratio of length to diameter of the cavity is greater than/or equal to 2 and less than/or equal to 10 ($2 \leq L/D \leq 10$) and where the diameter is greater than or equal to 5 mm ($D \geq 5$ mm)

NOTE See annex A.

3.21
inoculated carrier
carrier on which a defined number of test organisms has been deposited

[EN 866-1:1997, definition 3.8]

3.22
installation test
series of checks and tests performed after installation of the sterilizer in the place of use

[EN 554:1994, definition 3.9]

3.23
locked door
door with the locking device(s) fully engaged and where separate actions are required to unlock and open the door

3.24
maximum allowable pressure
maximum pressure for which the equipment is designed

[EN 764-1:2004, definition 4.9]

NOTE 1 The maximum allowable pressure is specified by the manufacturer for a specific location. This is the location of connection of protective and/or limiting devices or the top of equipment or if not appropriate any other point specified.

NOTE 2 See Pressure Equipment Directive 97/23/EC, article 1, clause 2.3.

3.25
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

[EN ISO 13485:2003, definition 3.7].

3.26
monitoring
function of a device or person to check the attainment of the pre-set cycle parameters essential to the efficacy of the operating cycle

3.27
operating pressure
fluid pressure occurring during specified operating conditions

[EN 764:2004, definition 4.8]

NOTE For the purposes of steam sterilization operating pressure is specified for the plateau period of a sterilization cycle.

3.28
plateau period
equilibration time plus the holding time

[EN 285:1996, definition 3.24]

3.29
porous
ability of a material or configuration of material(s) to absorb fluids

3.30
pressure vessel
vessel describing the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent open connection with the sterilizer chamber

[EN 285:1996, definition 3.25]

3.31
process challenge device (PCD)
object which simulates the worst case of conditions for attainment of the specified sterilization conditions within the items to be sterilized

[EN 867-5:2001, definition 3.2]

NOTE The device is so constructed that a biological or non-biological indicator system can be placed within the device in the position which it is most difficult for the sterilizing agent to reach. The design of the process challenge device depends on the nature of the goods to be sterilized and the sterilization procedure.

3.32
hazard
potentially detrimental effect on persons or the surroundings arising directly from either the sterilizer or its load

3.33
saturated steam
water vapour at a temperature corresponding to the boiling point of the source liquid

[EN 554:1994, definition 3.20]

3.34
small steam sterilizer
steam sterilizer which is unable to accommodate a sterilization module and has a chamber volume not exceeding 60 litres

3.35
solid
product that is not made from porous material and which has no recesses or features which present a greater or equal challenge to steam penetration than hollow load B

3.36
sterile
condition of a medical device that is free from viable micro-organisms

[EN 556-1:2001, definition 3.4]

3.37
sterilization
process undertaken to render a sterilizer load sterile

[EN 285:1996, definition 3.31]

3.38
sterilization cycle
automatic sequence of operating stages performed in a sterilizer for the purpose of sterilization

[EN 285:1996, definition 3.32]

3.39
sterilization cycle type
classification of a sterilization process based on the performance of the cycle

NOTE 1 These categories are demonstrated by compliance with relevant tests listed in this standard

NOTE 2 This standard defines three sterilization cycle types: B, N and S. Other claims may be made, but should not make reference to the sterilization cycle type listed.

3.40
sterilization module
imaginary rectangular parallelepiped of dimensions 300 mm × 300 mm × 600 mm used to express the usable space of sterilizers

3.41
sterilization temperature
minimum temperature of the sterilization temperature band

[EN 554:1994, definition 3.24]

3.42
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 554:1994, definition 3.25]

NOTE These temperatures are usually stated in whole degrees Celsius.

3.43
sterilizer
apparatus designed to achieve sterilization

[EN 285:1996, definition 3.36]

3.44
sterilizer chamber
part of the sterilizer which receives the sterilizer load

[EN 554:1994, definition 3.27]

3.45
sterilizer load
goods that are to be sterilized simultaneously in the same sterilizer chamber

[EN 554:1994, definition 3.28]

3.46
temperature measurement reference position
position for temperature measurement as identified by the manufacturer to represent the conditions in the usable space

3.47
theoretical steam temperature
temperature of saturated steam expressed in Kelvin, calculated from the measured pressure, using the following equation:

$$T = A + B\,(\ln P + C)^{-1}\ ^{5)} \qquad (1)$$

5 IRVINE TH.F., LILEY, P.E., Steam and Gas tables with computer equations. *Academic Press*, 1984.

where

T is the theoretical steam temperature in Kelvin;

P is the measured pressure in megapascals, time averaged to result in a time constant between 1 s and 2,5 s;

A is 42,677 6 K;

B is –3 892,70 K;

C is –9,486 54

3.48
type test
series of checks and tests for a particular design of sterilizer to demonstrate compliance with the requirements of this standard

3.49
unloading door
door in a double ended sterilizer through which the sterilized load is removed from the sterilizer chamber after a sterilization cycle

[EN 285:1996, definition 3.42]

3.50
usable space of small steam sterilizers
space inside the sterilizer chamber which is not restricted by fixed parts or the appropriate furniture as specified by the manufacturer of the sterilizer for the intended use and which is consequently available to accept the sterilizer load

3.51
validation
documented procedure for obtaining, recording and interpreting data required to show that a process will consistently comply with pre-determined specifications

[EN 554:1994, definition 3.29]

3.52
water charge
volume of the water in the vessel from which the steam for the sterilization cycle is generated

3.53
works test
series of tests performed at the manufacturer's works to demonstrate compliance of each sterilizer with its specification

[EN 285:1996, definition 3.44]

4 General technical requirements

4.1 Dimensions

The usable space shall be insufficient in size to accommodate a sterilization module.

4.2 Materials

The materials used for components in contact with steam, including instrumentation, shall:

— resist the attack of steam and condensate;

— not lead to deterioration of the quality of the steam;

— not release any substances in such quantities that they could constitute an environmental or health risk.

NOTE 1 EN 285:1996, annex A suggests materials and combinations of materials that are suitable for specified applications in the construction of steam sterilizers.

NOTE 2 Materials should be assessed in accordance with the principles of EN ISO 10993.

4.3 Design and construction

4.3.1 Doors and locking devices

4.3.1.1 The door shall be capable of being closed without being locked, so that it can be re-opened and closed before a sterilization cycle is initiated.

4.3.1.2 When fitted, the door seal shall permit ease of cleaning of the contact surfaces and seal replacement.

4.3.1.3 After cycle start it shall not be possible to open a sterilizer door before cycle complete is indicated, except through special intervention that will lead to a fault indication.

4.3.1.4 For double ended sterilizers it shall not be possible for more than one door to be open at a time, except for maintenance purposes.

4.3.1.5 For double ended sterilizers it shall not be possible to open the unloading door before cycle complete is indicated.

4.3.2 Test connection(s)

4.3.2.1 The sterilizer shall be equipped with at least one standard test connection.

4.3.2.2 The test connection(s) shall have a female pipe thread conforming to EN ISO 228-G¼ according to EN ISO 228-1.

4.3.2.3 The test connection(s) shall be at a point of easy access to the chamber. The test connection(s) shall be clearly marked.

4.3.2.4 The steam inlet or vacuum ports and pipelines shall not be used for test connections.

4.3.3 Air filter

4.3.3.1 The air admitted to return the sterilizer chamber to atmospheric pressure after a vacuum assisted drying stage shall be admitted through a filter.