SLOVENSKI STANDARD
SIST EN 13060:2015

01-marec-2015

Nadomešča:
SIST EN 13060:2005+A2:2010

Mali parni sterilizatorji

Small steam sterilizers

Dampf-Klein-Sterilisatoren

Petits stérilisateurs à la vapeur d'eau

Ta slovenski standard je istoveten z: EN 13060:2014

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

SIST EN 13060:2015 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 13060

December 2014

ICS 11.080.10

Supersedes EN 13060:2004+A2:2010

English Version

Small steam sterilizers

Petits stérilisateurs à la vapeur d'eau

Dampf-Klein-Sterilisatoren

This European Standard was approved by CEN on 15 November 2014.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 13060:2014 E

Contents

Page

Foreword

This document (EN 13060:2014) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2015 and conflicting national standards shall be withdrawn at the latest by December 2015.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 13060:2004+A2:2010.

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 following amendments have been made in comparison with EN 13060:2004+A2:2010:

a) The scope of the standard has been revised with the aim to define small and large sterilizers on the chamber volume;

b) Normative references, terms and definitions have been updated, e.g.

   — term “hollow load A” has been changed to become “narrow lumen” (3.18)

   — term “hollow load B” has been changed to become “simple hollow items” (3.30)

c) In Clause 4 various sub-clauses and relevant requirements have been added, such as:

   — General requirements for design and construction (4.3.1),

   — Vibrations (4.3.5)

   — Noise (4.3.6)

   — Steam penetration test (4.5.1.6)

   — Software (4.5.4);

d) Sub-clause 4.8 has been divided into two subsections:

   — 4.8 Information to be provided

   — 4.9 Marking

e) Requirements in 5.3 on Attainment of the sterilization conditions have been revised;

f) Requirements in Clause 6 Safety, risk control and usability have been revised, e.g. requirements on electromagnetic compatibility (EMC), Pressure Equipment and risk control were added

g) Requirements on Sound power level (7.2.6) were added;

h) Requirements in 8.6 Porous load have been revised;

i) Requirements for Process challenge device (PCD) and chemical indicators for products with narrow lumen were revised;

j) Annex A has been revised, e.g. the defined hollow load A and B replaced by products with narrow lumen or simple hollow items;

k) Example for process challenge device for narrow lumen (PCD) has been moved to a new Annex G.

l) Annex ZA including Table ZA.1 on medical device directive and Table ZA.2 on machinery directive have been updated due to the changes made in the standard;

m) Standard has been editorially revised;

n) Updated Bibliography.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

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

This European Standard specifies the general requirements for small steam sterilizers and associated test methods. Performance is defined by reference to standard test loads. These are used to define a basic minimum performance and are not necessarily related to specific medical devices. It is the responsibility of the user and the manufacturer of the device to be sterilized to determine that any particular cycle is suitable for sterilizing a particular device. The performance tests specified in this standard can also be used by the manufacturer of the device to be sterilized 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. This will enable users to identify the specific sterilizer performance required to safely process their devices.

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

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 product. Therefore the suitability of a sterilization procedure for a particular product needs to be verified by validation (see EN ISO 17665-1).

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 with a chamber volume of less than 60 l and unable to accommodate a sterilization module (300 mm × 300 mm × 600 mm).

The requirements concerning the quality management and risk management are addressed by other standards (e.g. EN ISO 13485, EN ISO 14971).

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 ISO 17665-1.

This European Standard does not specify requirements for other sterilization processes that also employ moist heat as part of the process (i.e. formaldehyde, ethylene oxide).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

prEN 285:2014[1)], *Sterilization — Steam sterilizers — Large sterilizers*

EN 285: 2006+A2:2009, *Sterilization — Steam sterilizers — Large sterilizers*

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 for terminally sterilized medical devices* [2)]

EN 1041, *Information supplied by the manufacturer of medical devices*

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

---

1) Under revision.

2) EN 868-1 has been replaced by EN ISO 11607-1.

EN 13060:2004+A2:2010, *Small steam sterilizers*

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

EN 60529, *Degrees of protection provided by enclosures (IP Code)(IEC 60529)*

EN 60751:2008, *Industrial platinum resistance thermometers and platinum temperature sensors (IEC 60751:2008)*

EN 61010-1:2010, *Safety requirements for electrical equipment for measurement, control, and laboratory use — Part 1: General requirements (IEC 61010-1:2010)*

EN 61010-2-040:2005, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials (IEC 61010-2-040:2005)*

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

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

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

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

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

EN ISO 11138-3, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3)*

EN ISO 11140-1, *Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1)*

EN ISO 14971:2012, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)*

3 Terms and definitions

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

3.1
active drain
drain through which fluids present in the chamber are discharged during the process

3.2
automatic controller
⟨sterilization⟩ device that, in response to cycle parameters, operates the apparatus sequentially through the operating cycle(s)

3.3
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

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

3.4
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

[SOURCE: ISO/TS 11139:2006, definition 2.4]

3.5
chemical indicator
combination of the indicator agent and its substrate that reveals change in one or more process variables based on a chemical or physical change resulting from exposure to a process

Note 1 to entry: An indicator intended to be used only in combination with a specific test load is also termed an indicator (both together becoming an indicator system).

3.6
cycle parameter
physical value including its tolerances used for control, monitoring, indication and recording of the operating cycle

[SOURCE: prEN 285:2014, definition 3. 8, modified: “including its tolerances” was added]

3.7
double ended
with separate doors for loading and unloading

3.8
equilibration time
period which elapses between the attainment of the sterilization temperature in the usable chamber space and the attainment of the sterilization temperature at all points within the load

[SOURCE: EN ISO 17665-1:2006, definition 3.13, modified: ”at the reference measurement point” replaced by “in the usable chamber space”]

3.9
hazard
potential source of harm

[SOURCE: ISO/IEC Guide 51:1999, definition 3.5]

3.10
hazardous situation
circumstance in which people, property or the environment are exposed to one or more hazard(s)

[SOURCE: ISO/IEC Guide 51:1999, definition 3.6]

3.11
holding time
<small steam sterilizer> period for which the temperatures at all points within the useable chamber space and the load are continuously within the sterilization temperature band

Note 1 to entry: The holding time follows immediately after the equilibration time. The extent of the holding time is related to the sterilization temperature.

[SOURCE: EN ISO 17665-1:2006, definition 3.19, modified: “<small sterilizers>” added, ”at the reference measurement point and” deleted and “within the sterilization load” replaced by “within the usable chamber space and the load]

3.12
installation test
series of checks and tests performed during installation of the sterilizer in the place of use

3.13
instructions for use
instructions intended for the user (operator) of the sterilizer to enable safe and appropriate use

3.14
locked
with the locking device(s) fully engaged

3.15
maximum allowable pressure
maximum pressure for which the equipment is designed as specified by the manufacturer

Note 1 to entry: See Pressure Equipment Directive 97/23/EC, Article 1, sub-clause 2.3.

[SOURCE: EN 764-1:2004, definition 3.8, modified: addition of new Note 1 to entry]

3.16
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

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

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

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

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

[SOURCE: EN ISO 13485:2012, definition 3.7]

3.17
monitoring
checking against specifications

3.18
narrow lumen
hollow device which is beyond the range defined for a simple hollow item (see 3.30 and Figure A.3), and which is neither solid (see 3.32) nor porous (see 3.22)

Note 1 to entry: See Annex A.

EXAMPLES Long tubes, mating surfaces, hinged devices.

3.19
non-condensable gas
air and other gas which will not liquefy under the conditions of a saturated steam process

3.20
operating pressure
fluid pressure occurring during specified operating conditions

[SOURCE: EN 764-1:2004, definition 3.6]

Note 1 to entry: For the purposes of steam sterilization operating pressure is specified for the plateau period of a sterilization cycle.

3.21
plateau period
equilibration time plus the holding time

[SOURCE: prEN 285:2014, definition 3.23]

3.22
porous
permeable to water, air or other fluids

3.23
pre-purchase information
information necessary for prospective purchasers to enable them to make an informed purchasing decision

3.24
pressure vessel
housing and its direct attachments up to the coupling point connection it to other equipment, designed and built to contain fluids under pressure

Note 1 to entry: A vessel can be composed of more than one chamber.

[SOURCE: prEN 285:2014, definition 3.25]

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

[SOURCE: ISO/TS 11139:2006, definition 2.33]

3.26
reference measurement point
point where the temperature sensor used for the operating cycle control is located

[SOURCE: prEN 285:2014, definition 3.26, modified: "probes" replaced by "sensor"]

3.27
risk assessment
overall process comprising a risk analysis and a risk evaluation

[SOURCE: EN ISO 14971:2012, definition 2.18]

3.28
risk control
process through which decisions are reached and protective measures are implemented for reducing risks to, or maintaining risks within, specified levels

[SOURCE: EN ISO 14971:2012, definition 2.19, modified; “in” replaced by “through” and “made and measures” replaced by “reached and protective measures are]

3.29
saturated steam
water vapour in a state of equilibrium between its liquid phase and its gas phase

[SOURCE: EN ISO 17665-1:2006, definition 3.44, modified – “condensation and evaporation” replaced by “its liquid phase and its gas phase”]

3.30
simple hollow item
single-ended open-space items 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 items 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 1 to entry: See Annex A.

EXAMPLES Bowls, receivers.

3.31
small steam sterilizer
steam sterilizer which has a chamber volume of less than 60 litres and is unable to accommodate a sterilization module

3.32
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 a simple hollow item

3.33
sterile
free from viable microorganisms

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

3.34
sterile barrier system
minimum package that prevents ingress of microorganisms and allows aseptic presentation of product at the point of use

3.35
sterilization
validated process used to render a product free from viable microorganisms

Note 1 to entry: 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.

[SOURCE: ISO/TS 11139:2006, definition 2.47, modified: Note 1 to entry was added]

3.36
sterilization cycle
operating cycle performed by a sterilizer for the purpose of sterilization

3.37
sterilization cycle type
classification of a sterilization process based on the performance of the cycle

Note 1 to entry: For types of sterilization cycles see Table 1.

Table 1 — Types of sterilization cycles

Type	Description of intended use
B	The sterilization of products as represented by the test loads in the standard. For products that lie within the limits specified for the relevant test loads, this includes solid products, porous products and lumen devices, wrapped (single- and multiple-layer) or non-wrapped.
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, lumen devices, bowls and receivers, single-layer 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 for immediate use.	
NOTE 3 These categories are demonstrated by compliance with relevant tests listed in this standard.	

3.38
sterilization load
product to be, or that has been, sterilized together using a given sterilization process

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

3.39
sterilization module
rectangular parallelepiped of dimensions 300 mm (height) × 600 mm (length) × 300 mm (width)

[SOURCE: prEN 285:2014, definition 3.33]

3.40
sterilization process fault
one or more of the cycle parameters lying outside of its/their specified tolerance(s)

3.41
sterilization temperature
minimum temperature on which the evaluation of the sterilization efficacy is based