SLOVENSKI STANDARD
oSIST prEN 13060:2012

01-september-2012

Mali parni sterilizatorji

Small steam sterilizers

Dampf-Klein-Sterilisatoren

Ta slovenski standard je istoveten z: **prEN 13060 rev**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment

oSIST prEN 13060:2012 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 13060 rev

May 2012

ICS 11.080.10

Will supersede EN 13060:2004+A2:2010

English Version

Small steam sterilizers

Petits stérilisateurs à la vapeur d'eau

Dampf-Klein-Sterilisatoren

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (prEN 13060:2012) has been prepared by Technical Committee CEN/TC 102 “Sterilizers for medical purposes”, the secretariat of which is held by DIN.

This document is currently submitted to the CEN Enquiry.

This document will supersede 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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

The main changes with respect to the previous edition are listed below:

— Update of Normative references

—Update of Terms and definitions (certain definitions no longer referenced in the standard have been erased)

— Addition of Clause 4.3.1 (General requirements for design and construction)

— Addition of Clause 4.3.5 (Vibrations)

— Addition of Clause 4.3.6 (Noise)

— Addition of Clause 4.5.4 (Software)

— Deletion of Clause 4.7. (Electromagnetic compatibility)

— Modifications to Clause 4.8:

Clause 4.8 in EN 13060:2004 + A2:2010 (Marking and accompanying documents) was divided into two separate clause in PR EN 13060: Clause 4.8 (Information to be provided) and Clause 4.9 (Marking)

— Modifications to Clause 5.3

— Modifications to Clause 6 notably addition of requirements for EMC, pressure equipment and risk control

— Addition of Clause 7.2.6 (Sound power level)

— Modifications to Clause 8.6.1 (relative humidity required in point e)

— Deletion of Clause 8.6.2.2 (Reduced test pack)

— Deletion of Clause 8.6.3.2

— Modifications to Clause 8.10

— Modifications to Annex A to include both the definition for narrow lumens and for simple hollow items

— Addition of informative Annex G (Example of a PCD for narrow lumen)

—— Modifications to Annex ZA.1 relating to the "Medical Devices" Directive 93/42/EC (and modifying texts)

—— Modifications to Annex ZA.2 relating to the "Machinery" Directive 2006/42/EC (and modifying texts)

Limited modifications have also been made to the following sections in order to clarify:

—— Introduction, scope

—— 4.4.3.3 (erased normative reference to EN 475)

—— Modifications to Clauses 7.1, 7.2.1, 7.3.1, 7.3.2, 7.4.1, 8.1, 8.11 for clarification

—— Updated Bibliography

Introduction

Small steam sterilizers are widely used for medical purposes, e.g. in general medical practice, dentistry, 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 sterilizer 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 process cycle is suitable for sterilizing a particular device.

Test loads are:

— narrow lumen (formerly hollow loads A);

— simple hollow item (formerly hollow loads B);

— standard test pack for porous loads (wrapped);

— small porous items (wrapped);

— composition of metal bolts (wrapped or unwrapped).

These test loads are intended in general to represent kinds of real products having characteristics such as those of:

— solid products;

— hinged devices;

— porous loads;

— small porous items;

— lumen devices;

— bowls and receivers;

— unwrapped products; and

— wrapped products.

NOTE For wrapped products, single-layer or multiple-layer packaging systems should provide a sterile barrier system which conforms to EN ISO 11607-1.

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 17664:2004. 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 load. 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 litres 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 normative reference to 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, clauses 9 and 10 which are applicable to processes conducted by small steam sterilizers.

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.

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

EN ISO 11138-3:2009, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006).*

EN ISO 11140-1:2009, *Sterilization of health care products — Chemical indicators — Part 1: General requirement (ISO 11140-1:2005).*

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 868:2009 *(parts 2-10)*, *Packaging for terminally sterilized medical devices*[1].

EN 10088-1:2005, *Stainless steels — Part 1: List of stainless steels.*

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

EN ISO 14971:2009, *Medical devices — Application of risk management to medical devices.*

EN 60529:1992*, Degrees of protection provided by enclosures (IP code).*

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

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.*

EN 61326-1:2006, *Electrical equipment for measurement, control and laboratory use — EMC requirements — General requirements (IEC 61326-1:2005).*

EN ISO 228-1:2003, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation (ISO 228-1:2000).*

EN 1041:2008, *Information supplied by the manufacturer of medical devices.*

EN ISO 3746:2010, *Acoustics — Determination of sound power levels of noise sources using sound pressure — Survey method using and enveloping measurement surface over a reflecting plane (ISO 3746:2010).*

EN ISO 4017:2001, *Hexagon head screws — Product grades A and B (ISO 4017:1999).*

EN ISO 4126-1:2004, *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 14937:2009, *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 14937:2009).*

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).*

EN 13445:2009 (all parts), *Unfired pressure vessels*.

EN ISO 11607-1:2009, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006).*

3 Terms and definitions

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

3.1
active drain of small steam sterilizers
drain through which fluids present in the chamber are discharged during the process

3.2
automatic controller
<sterilization> device that, in response to pre-determined operating cycle variables, operates the sterilizer sequentially through the required stages of the cycle(s)

[SOURCE: EN ISO 17665-1:2006, 3.2]

3.3
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

3.4
double ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

[SOURCE:EN 285: 2006, 3.11]

3.5
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

[SOURCE:EN ISO 17665-1:2006, 3.13]

3.6
fault
one or more of the process parameters lying outside its/their specified tolerance(s)

[SOURCE:ISO/TS 11139:2006, 2.19]

3.7
hazard
potential source of harm

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

3.8
hazardous situation
circumstance in which people, property or the environment are exposed to one or more hazard(s)

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

3.9
holding time (small steam sterilizers)
period for which the temperature of all points within the usable space including the temperature measurement reference position is held 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.

3.10
installation test
series of checks and tests performed after installation of the sterilizer in the place of use

3.11
instructions for use
instructions intended for the user (operator) of the sterilizer to enable safe and appropriate use

3.12
locked (with respect to the door)
with the locking device(s) fully engaged

3.13
maximum allowable pressure
maximum pressure for which the equipment is designed as specified by the manufacturer

[SOURCE: EN 764-1:2004, 3.8]

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

3.14
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 13485:2003, 3.7; Directive 93/42/CEE concerning medical devices amended by Directive 2007/47/EC]

3.15
monitoring
function of a device or person to check the attainment of the pre-set process parameters essential to the efficacy of the operating cycle

3.16
narrow lumen (formerly hollow load A)
hollow device which is beyond the range defined for a simple hollow item (see 3.11 and Figure A.3), and which is neither solid (see 3.32) nor porous (see 3.20)

Note 1 to entry: See Annex A.

EXAMPLES Long tubes, mating surfaces, hinged devices

3.17
non-condensable gas
air and/or gas which will not liquefy under the conditions of a saturated steam process

3.18
operating pressure
fluid pressure occurring during specified operating conditions

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

NOTE 1 TO ENTRY For the purposes of steam sterilization operating pressure is specified for the plateau period of a sterilization cycle.

3.19
plateau period
equilibration time plus the holding time

[SOURCE: EN 285:2006, 3.23]

3.20
porous
ability of a material or configuration of material(s) to absorb fluids

3.21
pre-purchase information
information necessary for prospective purchasers to enable them to make an informed purchasing decision

3.22
pressure vessel
vessel compromising the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent connection with the sterilizer chamber

[SOURCE: EN 285:2006, 3.23]

3.23
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, 2.33]

3.24
process parameter
specified value for a process variable

[SOURCE: ISO/TS 11139:2006, 2.34]

Note 1 to entry: The specification for a sterilization process includes the process parameters and their tolerances.

3.25
process variable
condition within a sterilization process, changes in which alter microbicidal effectiveness

[ISO/TS 11139:2006, definition 2.35]

EXAMPLES Time, temperature, pressure, concentration, humidity, wavelength.

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

[SOURCE: EN 285:2006, 3.26]

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

[SOURCE: EN ISO 14971:2009, 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: 2009, 2.19]

3.29
saturated steam
water vapour in a state of equilibrium between condensation and evaporation

[SOURCE: ISO 17665-1:2006, 3.44], [SOURCE: ISO 13683:1997, 3.18]

3.30
simple hollow item (formerly hollow load B)
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 (300 mm × 300 mm × 600 mm)

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

[SOURCE: EN 556-1:2001, 3.4]

3.34
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 exponential and thus the survival of a microorganism on an individual item can be expressed in terms of probability. While this probability can be reduced to a very low number, it can never be reduced to zero.

[SOURCE: ISO/TS 11139:2006, 2.47]

3.35
sterilization cycle
operating cycle performed by a sterilizer for the purpose of sterilization

[SOURCE: EN 285:2006, 3.29]