ICS 11.080.10 SLOVENSKÁ TECHNICKÁ NORMA Jún 2019

STN	Malé parné sterilizátory	STN EN 13060+A1 84 7110

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/19

Obsahuje: EN 13060:2014+A1:2018

Oznámením tejto normy sa ruší
STN EN 13060 (84 7110) z októbra 2015

128333

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 13060:2014+A1

November 2018

ICS 11.080.10 Supersedes EN 13060:2014

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 and includes Amendment 1 approved by CEN on 24 June 2018.

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

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Ref. No. EN 13060:2014+A1:2018 E

Contents

Page

European foreword ... 4
Introduction ... 6
1 Scope ... 7
2 Normative references ... 7
3 Terms and definitions ... 8
4 General technical requirements ... 16
4.1 Dimensions ... 16
4.2 Materials ... 16
4.3 Design and construction ... 17
4.4 Instrumentation, indication and registration devices ... 18
4.5 Control systems ... 27
4.6 Process ... 29
4.7 Services and local environment ... 30
4.8 Information to be provided ... 31
4.9 Marking ... 35
4.10 Accessories ... 36
5 Performance requirements ... 36
5.1 General ... 36
5.2 Air leakage rate ... 37
5.3 Attainment of the sterilization conditions ... 37
5.4 Product compatibility ... 37
5.5 Drying ... 38
5.6 Microbicidal efficacy ... 38
5.7 Non-condensable gases ... 38
6 Safety, risk control and usability ... 38
6.1 General requirements ... 38
6.2 Requirements for EMC ... 39
6.3 Requirements for pressure equipment ... 39
6.4 Requirements for risk control ... 40
7 Categories of tests ... 40
7.1 General ... 40
7.2 Type tests ... 41
7.3 Works test ... 41
7.4 Installation tests ... 42
8 Test equipment ... 42
8.1 General ... 42
8.2 Temperature sensors ... 42
8.3 Thermometric recording instrument ... 43
8.4 Pressure measurement and recording instrument ... 43
8.5 Test equipment for the performance of the air leakage test ... 44
8.6 Porous load ... 45
8.7 Solid load, unwrapped ... 47

8.8 Solid load, single wrapped **47**
8.9 Solid load, double wrapped **47**
8.10 Process challenge device (PCD) and chemical indicator for narrow lumen **48**
8.11 Process challenge device and chemical indicator for simple hollow item **48**
8.12 Balance for load dryness test **49**

9 Test programme **49**

10 Test methods **51**
10.1 General requirements on technical tests **51**
10.2 Air leakage test **51**
10.3 Dynamic sterilizer chamber pressure test **53**
10.4 Empty chamber test **54**
10.5 Solid load test **54**
10.6 Narrow lumen test **54**
10.7 Simple hollow item test **55**
10.8 Small porous load test **56**
10.9 Full porous load test (single and double wrapped) **57**
10.10 Small porous items test (single and double wrapped) **58**
10.11 Solid load dryness test **58**
10.12 Porous load dryness test (small and full, single and double wrapped) **59**
10.13 Small porous items dryness test (single and double wrapped) **60**
10.14 Non-condensable gases test **60**
10.15 Microbiological test for solid loads **64**
10.16 Microbiological test for narrow lumens **64**
10.17 Microbiological test for simple hollow item **64**
10.18 Microbiological test for small porous loads **65**
10.19 Microbiological test for full porous loads **65**
10.20 Microbiological test for small porous items **66**

Annex A (informative) **Clarification of the definition of narrow lumens and simple hollow items (see 3.18 and 3.30)** **67**

Annex B (informative) **Process evaluation system** **69**

Annex C (informative) **Suggested maximum limits of contaminants in and specification for water for steam sterilization** **70**

Annex D (informative) **Example of a table to be supplied with pre-purchase documentation and with the instructions for use** **71**

Annex E (informative) **Load support systems** **72**

Annex F (informative) **Rationale for the tests** **73**

Annex G (informative) **Example of a process challenge device for narrow lumen** **76**

Annex ZA (informative) **Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC on medical devices** **77**

Bibliography **82**

European foreword

This document (EN 13060:2014+A1:2018) has been prepared by Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices”, 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 May 2019 and conflicting national standards shall be withdrawn at the latest by May 2019.

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

This document includes Amendment 1 approved by CEN on 24 June 2018.

This document supersedes EN 13060:2014.

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.

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, Serbia, 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.

[A1] For sterilizer models of a given design, that have been supplied to the market prior to publication of this edition of EN 13060, with the 4 K band as specified by EN 13060:2004+A2:2010, 5.3.2, these sterilizers can continue to be supplied to the market with the 4 K band. [A1]

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*

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

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1) Under revision.

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

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)*