Steriliseerimine. Aursterilisaatorid. Suured sterilisaatorid KONSOLIDEERITUD TEKST

Sterilization - Steam sterilizers - Large sterilizers
CONSOLIDATED TEXT

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 285:2006+A2:2009 sisaldab Euroopa standardi EN 285:2006+A2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 285:2006+A2:2009 consists of the English text of the European standard EN 285:2006+A2:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.06.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.06.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 06.05.2009.	Date of Availability of the European standard text 06.05.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.080.10

Võtmesõnad: lukustusseadised, meditsiiniaparatuur, mõõteriistad, näitmõõteriistad, seadmete tehnilised andmed, sterilisaatorid, steriliseerimine, tehnilised andmed, uksed, varustus, veeaur

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN 285:2006+A1:2008

English Version

Sterilization - Steam sterilizers - Large sterilizers

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

Sterilisation - Dampf-Sterilisatoren - Groß-Sterilisatoren

This European Standard was approved by CEN on 27 April 2006 and includes Amendment 1 approved by CEN on 4 February 2008 and Amendment 2 approved by CEN on 5 April 2009.

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

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Contents

Foreword

This document (EN 285:2006+A2:2009) 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of an identical text or by endorsement, at the latest by November 2009 and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2008-02-04 and Amendment 2, approved by CEN on 2009-04-05.

This document supersedes [A2] EN 285:2006+A1:2008 [/A2].

The start and finish of text introduced or altered by amendment is indicated in the text by tags [A1] [/A1] and [A2] [/A2].

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.

This document 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 (currently under revision, see prEN ISO 17665).

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

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and 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 medical devices and their accessories contained in one or more sterilization modules. The test loads described in this European Standard are selected to represent the majority of loads (i.e. wrapped goods consisting of metal, rubber and porous materials) for the evaluation of general purpose steam sterilizer for medical devices. However, specific loads (e.g. heavy metal objects or long and/or narrow lumen) will require the use of other test loads.

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

1.2 This European Standard is not applicable to steam sterilizers designed to process a size of load less than one sterilization module or having a chamber volume less than 60 l.

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 management systems e.g. EN ISO 13485.

1.4 Planning and design of products applying to this European Standard should consider the environmental impact from the product during its life cycle. Environmental aspects are addressed in Annex A.

NOTE Additional aspects of environmental impact are addressed in EN ISO 14971.

2 Normative references

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

EN 764-1:2004, *Pressure equipment — Part 1: Terminology — Pressure, temperature, volume, nominal size*

[A1] *deleted text* [A1]

EN 867-3, *Non-biological systems for use in sterilizers — Part 3: Specification for Class B indicators for use in the Bowie and Dick test*

[A1] EN 867-5, *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* [A1]

EN 868-5, *Packaging materials and systems for medical devices which are to be sterilized — Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction — Requirements and test methods*

EN 1822 (all parts), *High efficiency air filters (HEPA and ULPA)*

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

EN 10088-3, *Stainless steels — Part 3: Technical delivery conditions for semi-finished products, bars, rods, wire, sections and bright products of corrosion resistant steels for general purposes*

EN 12953 (all parts), *Shell boilers*

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

EN 14222, *Stainless steel shell boilers*

EN 60584-2:1993, *Thermocouples — Part 2: tolerances (IEC 60584-2:1982 + A1:1989)*

EN 60751:1995, *Industrial platinum resistance thermometer sensors (IEC 60751:1983 + A1:1986)*

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

EN 61010-2-040, *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 61326:1997, *Electrical equipment for measurement, control and laboratory use — EMC requirements (IEC 61326:1997)*

EN 61672-1:2003, *Electroacoustics — Sound level meters — Part 1: Specifications (IEC 61672-1:2002)*

EN 61672-2:2003, *Electroacoustics — Sound level meters — Part 2: Pattern evaluation tests (IEC 61672-2:2003)*

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)*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 764-1:2004 and the following apply.

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

3.1
access device
means used to permit access to restricted parts of the equipment

NOTE This may be by dedicated key, code or tool.

3.2
air removal
removal of air from the sterilizer chamber and sterilizer load 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
microbiological test system providing a defined resistance to a specified sterilization process

[ISO/TS 11139:2001, definition 2.4]