Nederlandse norm

NEN-EN 285

(en)

Sterilization - Steam sterilizers - Large sterilizers

Vervangt NEN-EN 285:1997;
NEN-EN 285:1997/C1:1998;
NEN-EN 285:2002 Ontw.

ICS 11.080.10

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- EN 285:2006,IDT

Normcommissie 301 081 "Steriliseren en sterilliteit"

NEN

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Postbus 5059, 2600 GB Delft
Telefoon (015) 2 690 390, Fax (015) 2 690 190

Nederlands voorwoord

Voor de in deze norm vermelde normatieve verwijzingen bestaan in Nederland de volgende equivalenten:

vermelde norm	Nederlandse norm	titel
EN 764-1:2004	NEN-EN 764-1:2004	Drukapparatuur - Deel 1: Terminologie, temperatuur, volume, nominale afmetingen (en)
EN 866-3	NEN-EN 866-3	Biologische indicatoren voor de beproeving van sterilisatoren en sterilisatieprocessen - Deel 3: Bijzondere systemen voor toepassing in sterilisatoren met vochtige warmte (en)
EN 867-3	NEN-EN 867-3	Niet-biologische indicatoren voor toepassing in sterilisatoren - Deel 3: Specificaties voor Klasse-B-indicatoren voor toepassing in de Bowie en Dick-proef (en)
EN 868-5	NEN-EN 868-5	Verpakkingsmateriaal en systemen voor te steriliseren medische hulpmiddelen - Deel 5: Warm lasbare laminaatzakken en warm lasbaar laminaat op rol vervaardigd van papier en kunststoffolie - Eisen en beproevingsmethoden (en)
EN 1822:series	NEN-EN 1822:reeks	Luchtfilters met hoog rendement
EN 10088-1	NEN-EN 10088-1	Roestvaste staalsoorten - Deel 1: Lijst van roestvaste staalsoorten (en,nl)
EN 10088-3	NEN-EN 10088-3	Roestvaste staalsoorten - Deel 3: Technische leveringsvoorwaarden voor halfproducten, staven, draad en profielen van corrosievaste staalsoorten voor algemene doeleinden (en,en)
EN 12953:series	NEN-EN 12953:reeks	Vlampijpketels
EN 13445:series	NEN-EN 13445:reeks	Niet aan vlambelasting blootgestelde drukvaten (en)
EN 14222	NEN-EN 14222	Vlampijpketels van corrosievast staal (en)
EN 60584-2:1993	NEN 10584-2:1993	Thermokoppels - Deel 2: Toleranties in meetwaarden (en,fr)

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 285

May 2006

ICS 11.080.10

Supersedes EN 285:1996

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.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

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Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 285:2006: E

Contents

Foreword

This document (EN 285:2006) 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 2006, and conflicting national standards shall be withdrawn at the latest by November 2008.

This document supersedes EN 285:1996.

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, 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*

EN 866-3, *Biological systems for testing sterilizers and sterilization processes — Part 3: Particular systems for use in moist heat sterilizers*[1)]

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*

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)*

1) Currently under revision.

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]

3.5
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 realized by standards

[IVM:1994, definition 6.11]

3.6
chamber depth
depth of the sterilizer chamber which is available for the sterilizer load

3.7
chamber height
height of the sterilizer chamber which is available for the sterilizer load

3.8
chamber width
width of the sterilizer chamber which is available for the sterilizer load

3.9
cycle complete
indication that the sterilization cycle has been completed according to programme and that the sterilized load is ready for removal from the sterilizer chamber

3.10
door
lid or similar device provided as a means of closing and sealing the sterilizer chamber

3.11
double ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

3.12
equilibration time
period which elapses between the attainment of the sterilization temperature at the reference measurement point and the attainment of the sterilization temperature at all points within the load

3.13
holding time
period for which the temperatures at the reference measurement point and at all points within the load are continuously 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.

3.14
inoculated carrier
carrier on which a defined number of test organisms has been deposited

[EN 866-1:1997, definition 3.8]

3.15
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[ISO/TS 11139:2001, definition 2.20]

3.16
loading door
door in a double ended sterilizer through which the sterilizer load is put into the sterilizer chamber prior to sterilization

3.17
medical device
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]

3.18
non-condensable gas
air and other gas which will not condense under the conditions of steam sterilization

3.19
operating cycle
sequence of operating stages which is performed automatically by a sterilizer

3.20
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[ISO/TS 11139:2001, definition 2.24]

3.21
operator
person operating equipment for its intended purpose

3.22
plateau period
equilibration time plus the holding time

3.23
pressure vessel
vessel comprising the sterilizer chamber, jacket (if fitted), door(s) and components that are in permanent connection with the sterilizer chamber

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