Nederlandse norm

NEN-EN 14180+A1

(en)

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Vervangt NEN-EN 14180:2003;
NEN-EN 14180:2003/Ontw. A1:2009

ICS 11.080.10

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Als Nederlandse norm is aanvaard:
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Normcommissie 301081 "Steriliseren en steriliteit"

NEN

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Nederlands voorwoord

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

vermelde norm	Nederlandse norm	titel
EN 866-1	NEN-EN 866-1	Biologische indicatoren voor de beproeving van sterilisatoren en sterilisatieprocessen - Deel 1: Algemene eisen
EN 866-5	NEN-EN 866-5	Biologische indicatoren voor de beproeving van sterilisatoren en sterilisatieprocessen - Deel 5: Specifieke systemen voor toepassing in formaldehydesterilisatoren met gebruik van lage-temperatuurstoom
EN 867-5	NEN-EN 867-5	Niet-biologische indicatoren voor toepassing in sterilisatoren - Deel 5: Specificaties voor indicatorsystemen en proefstukken voor de prestatiebeproeving van kleine sterilisatoren van type B en type S
EN 868-5	NEN-EN 868-5	Verpakkingsmateriaal voor te steriliseren medische hulpmiddelen - Deel 5: Af te sluiten zakken en spoelen van poreus materiaal en plastic film constructie - Eisen en beproevingsmethoden
EN 60584-2	NEN 10584-2	Thermokoppels - Deel 2: Toleranties in meetwaarden
EN 60751	NEN-EN-IEC 60751	Temperatuuropnemers met platinaweerstand en thermometers met temperatuuropnemers met platinaweerstand voor industrieel gebruik
EN 61010-1	NEN-EN-IEC 61010-1	Veiligheidseisen voor elektrisch materieel voor meet- en regeltechniek en laboratoriumgebruik - Deel 1: Algemene eisen
EN 61010-2-042:1997	NEN-EN-IEC 61010-2-042:1997	Veiligheidseisen voor elektrisch materieel voor meet- en regeltechniek en laboratoriumgebruik - Deel 2-042: Bijzondere eisen voor autoclaven en sterilisatoren met gebruik van giftige gassen voor de behandeling van medische benodigdheden en voor laboratoriumproeven
EN 61326:1997	NEN-EN-IEC 61326-1:1997	Elektrische uitrusting voor meting, besturing en laboratoriumgebruik - EMC-eisen - Deel 1: Algemene eisen
EN ISO 3746	NEN-EN-ISO 3746	Akoestiek - Bepaling van geluidvermogenniveaus van geluidbronnen - Globale methode met gebruik van een omhullend meetoppervlak boven een reflecterend oppervlak
ISO 228-1	NEN-EN-ISO 228-1	Niet-afdichtende pijpschroefdraad - Deel 1: Afmetingen, toleranties en aanduiding

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14180:2003+A1

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ICS 11.080.10

Replaces EN 14180:2003

English Version

Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

Stérilisateurs à usage médical - Stérilisateurs à la vapeur et au formaldéhyde à basse température - Exigences et essais

Sterilisatoren für medizinische Zwecke - Niedertemperatur-Dampf-Formaldehyd-Sterilisatoren - Anforderungen und Prüfung

This European Standard was approved by CEN on 16 May 2003 and includes Amendment 1 approved by CEN on 12 April 2009.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 14180:2003+A1:2009: E

Contents

Foreword

This document (EN 14180:2003+A1:2009) 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 2009-04-12.

This document supersedes EN 14180:2003.

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.

Annexes A, B, C and D are normative and form part of this European Standard.

Annexes E, F and ZA are for information only.

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.

Introduction

This European Standard specifies minimum requirements and test methods for sterilizers working below ambient atmospheric pressure performing a low temperature steam and formaldehyde (LTSF) process.

LTSF sterilizers are primarily used for the sterilization of medical devices in health care facilities, but may also be used during the commercial production of medical devices.

LTSF processes are specified by physical parameters and verified using physical, chemical and microbiological means. The sterilizers operate automatically using pre-set cycles.

The test methods and test equipment given may also be applicable to validation and routine control.

Validation and routine control of sterilization processes are essential to ensure their efficacy. This standard does not cover validation and routine control of a LTSF process. General criteria for validation and routine control of a sterilization process, also applicable to LTSF sterilization processes, are given in EN ISO 14937.

At the present state of knowledge, LTSF sterilizers should not be assumed to deliver processes effectively inactivating the causative agents of spongiform encephalopathies such as scrapie, Bovine Spongiform Encephalophaty and Creutzfeld-Jakob Disease. Specific recommendations have been produced in particular countries for the processing of materials potentially contaminated with these agents. (See also EN ISO 14937:2000, 1.6 Note 2).

Planning and design of products applying to this standard should consider not only technical issues but also the environmental impact from the product during its life-cycle. Environmental aspects are addressed in annex F of this standard.

NOTE Risk analysis methods, e. g. in EN ISO 14971, pay attention to environmental aspects.

Specifications on operator safety are addressed in EN 61010–1, EN 61010–2–042 and are not repeated in this standard. EN 60204–1 may also give valuable guidelines.

1 Scope

This European Standard specifies requirements and tests for LTSF sterilizers, which use a mixture of low temperature steam and formaldehyde as sterilizing agent, and which are working below ambient pressure only.

These sterilizers are primarily used for the sterilization of heat labile medical devices in health care facilities.

This European Standard specifies minimum requirements:

— for the performance and design of sterilizers to ensure that the process is capable of sterilizing medical devices;

— for the equipment and controls of these sterilizers necessary for the validation and routine control of the sterilization processes.

2 Normative references

[A1] 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. [A1]

EN 866–1, *Biological systems for testing sterilizers and sterilization processes — Part 1: General requirements.*[1]

EN 866–5, *Biological systems for testing sterilizers and sterilization processes — Part 5: Particular systems for use in low temperature steam and formaldehyde sterilizers.* [2]

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.*

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

EN 60584–2, *Thermocouples — Part 2: Tolerances (IEC 60584–2:1982 + A1:1989).*

EN 60751, *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 61010–2–042:1997, *Safety requirements for electrical equipment for measurement, control and laboratory use — Part 2–042: (Particular requirements for autoclaves and sterilizers using toxic gas for the treatment of medical materials, and for laboratory processes (IEC 61010–2–042:1997).*

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

EN ISO 3746, *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).*

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

3 Terms and definitions

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

3.1
access device
means used to enable access to restricted parts of equipment

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

3.2
aeration
a part or parts of the sterilization process in which defined conditions are used such that formaldehyde and its reaction products are desorbed from the medical device, and which can be performed within the sterilizer, within a separate room or chamber, or by a combination of the two

3.3
air removal
removal of air from the sterilizer chamber and sterilization load to facilitate sterilant penetration

3.4
automatic controller
device that, in response to pre-determined cycle variables, operates the sterilizer sequentially through the required stages of the operating cycle

[1] Under revision, see new edition of ISO 11138 series which is currently being prepared by ISO/TC 198, Vienna Agreement.

[2] Under revision, see new edition of ISO 11138 series which is currently being prepared by ISO/TC 198, Vienna Agreement.

3.5
biological indicator
an inoculated carrier contained within its primary pack ready for use

[EN 866–1:1997, definition 3.1]

3.6
chamber pre-heating
the heating of inner sterilizer-chamber surfaces to achieve predetermined temperatures prior to the commencement of a sterilization cycle

3.7
conditioning
treatment of product within the sterilization cycle, but prior to the holding time, to attain a predetermined temperature and humidity throughout the sterilization load

3.8
cycle complete
indication that the operating cycle has been satisfactorily completed and that the sterilized load is ready for removal from the sterilizer chamber

[EN 285:1996, definition 3.10]

3.9
cycle parameter
specified value for a cycle variable

3.10
cycle variables
the physical properties that influence the efficacy of the sterilization cycle

NOTE For LTSF-sterilizers, the cycle variables include, but may not be limited to temperature, pressure, time, sterilant concentration.

3.11
desorption
removal of the sterilant from the chamber and the load at the end of the exposure time

3.12
double-ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

[EN 285:1996, definition 3.13]

3.13
equilibration time
period which elapses between the attainment of the sterilization temperature at the reference measuring point and the attainment of the sterilization temperature at all points within the load

3.14
exposure time
time between introducing the sterilant into the chamber and the start of the desorption phase

3.15
holding time
period for which the temperature, the steam pressure and the formaldehyde concentration of the steam are held within pre-set values and their tolerances to achieve the required inactivation efficacy in the sterilizer chamber

NOTE The holding time follows immediately after the equilibration time.

3.16
inoculated carrier
a carrier on which a defined number of test organisms has been deposited

[EN 866-1:1997, definition 3.8]

3.17
installation qualification
IQ
obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[EN ISO 14937:2000, definition 3.9]

3.18
loading door
door in a double-ended sterilizer through which the sterilizer load is put into the sterilizer chamber prior to sterilization

[EN 285:1996, definition 3.21] (See also 3.43 unloading door)

3.19
medical device
any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

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

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

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

— control of conception,

and which does not achieve its principal 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 13485:2000, definition 3.1]

3.20
microbicidal solution
aqueous solution containing formaldehyde to feed the vaporiser for generating sterilant in the sterilizer

3.21
operating cycle
the automatic sequence of operating stages performed in a sterilizer

[EN 1422:1997, definition 3.24]

3.22
operational qualification
OQ
process of obtaining and documenting evidence that installed equipment operates within predetermined limits when used in accordance with its operational procedures

[EN ISO 14937:2000, definition 3.12]

3.23
operator
person operating equipment for its intended purpose

3.24
override
means intended only for maintenance or safety, by which the operating cycle can be interrupted or modified

3.25
post-cycle flushing
stage after "cycle complete" indication, during which the sterilization load is left in the closed chamber and the internal chamber atmosphere is exchanged

3.26
pressure vessel
a vessel consisting of the sterilizer chamber, door(s) and other components that form a permanent unit with the sterilizer chamber and that are pressurised by the same pressure

3.27
process challenge device
item designed to simulate product and used to assess the penetration performance of the sterilization cycle

NOTE The device is so constituted that a biological or chemical indicator can be put in the place which is the most difficult to reach by sterilizing agent(s).The indicator should not interfere with the function of the process challenge device.

3.28
production test
series of tests performed to demonstrate compliance of each sterilizer with its type test performance

3.29
reference measuring point
the point where the temperature sensor for the sterilization cycle control is located

3.30
requalification
repetition of part of validation for the purpose of confirming the continued acceptability of a specified process [EN ISO 14937:2000, definition 3.20]

3.31
sterilant
microbicidal agent composed of steam containing formaldehyde

3.32
sterilant injection
single or repeated stage beginning with the introduction of sterilant into the evacuated sterilizer chamber and ending when the set operating pressure has been attained

3.33
sterile
free from viable micro-organisms

[EN ISO 14937:2000, definition 3.23]

3.34
sterilization
validated process used to render a product free from viable micro-organisms

NOTE In a sterilization process the nature of microbial inactivation is described by an exponential function. Therefore the presence of a viable micro-organism on any individual item can be expressed in terms of probability. This probability may be reduced to a very low number, it can never be reduced to zero.

3.35
sterilizer
apparatus designed to achieve sterilization

[EN 285:1996, 3.36]

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