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Sterilisatorer för medicinskt bruk – Lågtemperatur ång- och formaldehyd sterilisatorer – Krav och provningsmetoder

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

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Europastandarden EN 14180:2014 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 14180:2014.

Denna standard ersätter SS-EN 14180+A2:2009, utgåva 1.

The European Standard EN 14180:2014 has the status of a Swedish Standard. This document contains the official version of EN 14180:2014.

This standard supersedes the Swedish Standard SS-EN 14180+A2:2009, edition 1.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Sterilisering av medicintekniska produkter, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 14180

May 2014

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Supersedes EN 14180:2003+A2:2009

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 10 April 2014.

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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (EN 14180:2014) 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 2014 and conflicting national standards shall be withdrawn at the latest by November 2014.

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

This document supersedes EN 14180:2003+A2:2009.

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 standard is a full technical revision of the previous version. The following amendments have been made in comparison to EN 14180:2003+A2:2009:

— normative references were updated;

— terms risk assessment, risk analysis and software validation were added;

— align biological testing with method from EN ISO 25424;

— requirements for heat isolation were updated;

— safety requirements, mainly as a consequence of compliance with the machinery directive were added;

— requirements and testing for sound power, also including vibration, were updated;

— Annex ZA including Tables ZA1 and ZA2 were updated.

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, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the 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 can 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 [8]. The sterilizers operate automatically using pre-set cycles.

The test methods and test equipment given could 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. Criteria for validation and routine control of LTSF sterilization processes are given in EN ISO 25424.

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 Encephalopathy 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 25424:2011, 1.2.1.

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 Specifications on operator safety are addressed in EN 61010–1, EN 61010–2–040 and are not repeated in this standard. EN 60204–1 can 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

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 764-7, *Pressure equipment - Part 7: Safety systems for unfired pressure equipment*

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 for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods*

EN 14222:2003, *Stainless steel shell boilers*

EN 60584–2, *Thermocouples — Part 2: Tolerances*

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

EN ISO 1874-1, *Plastics - Polyamide (PA) moulding and extrusion materials - Part 1: Designation system and basis for specification (ISO 1874-1)*

EN ISO 3746:2010, *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 3746:2010)*

EN ISO 11138-1:2006, *Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2006)*

EN ISO 11138-5, *Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5)*

EN ISO 14971:2012, *Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

EN ISO 15223-1, *Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1)*

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 1 to entry: This can be a dedicated key, code or tool.

3.2
aeration
part of the sterilization process during which sterilizing agent and/or its reaction products desorb from the medical device until predetermined levels are reached

Note 1 to entry: This can be performed within the sterilizer and/or in a separate chamber or room.

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 cycle parameters, operates the apparatus sequentially through the operating cycle(s)

3.5
biological indicator
test system containing viable microorganisms providing a defined resistance to a specified sterilization process

[SOURCE: ISO/TS 11139:2006, 2.3]

3.6
chamber pre-heating
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, humidity and, if applicable, concentration throughout the sterilization load

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

[SOURCE: EN 285:2006+A2:2009, 3.9]

3.9
cycle parameter
specified value for a cycle variable

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

3.10
cycle variable
physical property that influences the efficacy of the operating cycle

Note 1 to entry: For LTSF-sterilizers, the cycle variables include, but are not necessarily 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
desorption indicator
indicator, intended to determine the amount of sterilant residuals

3.13
double-ended sterilizer
sterilizer in which there is a door at each end of the sterilizer chamber

[SOURCE: EN 285:2006+A2:2009, 3.11]

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

3.15
inoculated carrier
supporting material on or in which a defined number of viable test organisms have been deposited

[SOURCE: EN ISO 11138-1:2006, 3.10]

3.16
installation qualification
IQ
process of obtaining and documenting evidence that equipment has been provided and installed in accordance with its specification

[SOURCE: ISO/TS 11139:2006, 2.22]

3.17
loading door
door in a double ended sterilizer through which the load is put into the sterilizer chamber

[SOURCE: EN 285:2006+A2:2009, 3.17]

Note 1 to entry: See also 3.47 unloading door.

3.18
LTSF-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