Meditsiinilised steriliseerijad. Madaltemperatuuriga auru ja formaldehüüdi kasutavad steriliseerijad. Nõuded ja katsetamine KONSOLIDEERITUD TEKST

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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 14180:2003+A2:2009 sisaldab Euroopa standardi EN 14180:2003+A2:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 14180:2003+A2:2009 consists of the English text of the European standard EN 14180:2003+A2:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.09.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.09.2009 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 15.07.2009.	Date of Availability of the European standard text 15.07.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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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 and Amendment 2 approved by CEN on 13 June 2009.

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Contents

Foreword

This document (EN 14180:2003+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of an identical text or by endorsement, at the latest by January 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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 and Amendment 2, approved by CEN on 2009-06-13.

This document supersedes [A2] EN 14180:2003+A1:2009 [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.

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.

[A2] 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 15424.

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 15424:2007 1.2.1). [A2]

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, [A2] EN 61010–2–040 [A2] 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]

[A2] *deleted text* [A2]

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).*

[A2] 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)* [A2]

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).*

[A2] EN ISO 11138-1, *Sterilization of health care products — Biological indicators — Part 1: General requirements (ISO 11138-1:2006)* [A2]

[A2] EN ISO 11138-5, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes (ISO 11138-5:2006)* [A2]

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

[A1] For the purposes of this document, the following terms and definitions apply. [A1]

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

[A2]

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