Sterilisaatorid meditsiiniliseks otstarbeks. Etüleenoksiidsterilisaatorid. Nõuded ja katsemeetodid KONSOLIDEERITUD TEKST

Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods CONSOLIDATED TEXT

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 1422:1999+A1:2009 sisaldab Euroopa standardi EN 1422:1997+A1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 1422:1999+A1:2009 consists of the English text of the European standard EN 1422:1997+A1:2009.
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.
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Võtmesõnad: etüleenoksiid, funktsionaalsuse hindamine, informatsioon, meditsiiniaparatuur, mõõtmed, märgistus, määratlused, ohutus, seadmete tehnilised andmed, sterilisaatorid, steriliseerimine, tehnilised andmed, testimine

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Sterilisatoren für medizinische Zwecke - Ethylenoxid-Sterilisatoren - Anforderungen und Prüfverfahren

This European Standard was approved by CEN on 30 August 1997 and includes Corrigendum 1 issued by CEN on 24 July 2002 and Amendment 1 approved by CEN on 12 April 2009.

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Foreword

This document (EN 1422:1997+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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 European Standard was approved by CEN on 30 August 1997 and includes Corrigendum 1 issued by CEN on 24 July 2002 and Amendment 1 approved by CEN on 12 April 2009.

This document supersedes EN 1422:1997.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩.

The modifications of the related CEN Corrigendum have been implemented at the appropriate places in the text and are indicated by the tags ⟨AC⟩ ⟨AC⟩.

This European Standard 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 standard.

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 requirements for ethylene oxide sterilizers working above or below atmospheric pressure. The specification describes minimum performance and construction requirements for ethylene oxide sterilizers in two types:

Type A – user programmable sterilizers;

Type B – sterilizers of limited size with one or more pre-set operating cycles.

Type A sterilizers are particularly suitable for industrial use when a sterilization cycle can be required that is specific to a limited range of medical devices.

Type B sterilizers are particularly suitable for use in the sterilization of heat labile medical devices processed in healthcare facilities. Users of ethylene oxide sterilizers in healthcare facilities should be particularly aware of the following:

a) the difficulty in validating and monitoring suitable cleaning processes prior to sterilization;

b) the difficulty in carrying out representative performance qualification studies for the wide variety of loading patterns that can be used;

c) the difficulty in carrying out meaningful bioburden studies on small numbers of widely differing medical devices to be sterilized (see EN 1174);

d) the problems associated with determining the levels of residual ethylene oxide and its reaction products when small numbers of widely differing medical devices are processed (see EN ISO 10993-7);

e) the need for specialist technical resource dedicated to the operation and maintenance of the equipment.

For type B sterilizers, a standard biological performance test has been specified for the pre-programmed sterilization cycle(s). This is not equivalent to validation. Attainment of sterilization conditions should be assured by validation procedures. Appropriate procedures for validation and routine monitoring of ethylene oxide sterilization processes used in the manufacture of medical devices are described in EN 550.

It is essential that a sterilizer is used only for sterilizing the goods which are compatible with the sterilization process. Ethylene oxide sterilizers should not be used for sterilizing goods which can be steam sterilized.

For the routine monitoring of the efficacy of each sterilizing cycle, it is demonstrated that the attained level of each cycle variable is meeting or exceeding the minimum value determined during validation. The instrumentation specified for the sterilizer is intended to allow adequate monitoring of all the physical variables. However the complexity of the ethylene oxide process is such that, with current monitoring and validation techniques, it is usually regarded as necessary to monitor each cycle with a number of biological indicators. Biological indicators suitable for this purpose are described in EN 866-1, EN 866-2 and prEN 866-8.

Ethylene oxide is a highly reactive chemical which can present a toxicity, flammability or explosivity hazard if incorrectly handled. Ethylene oxide sterilizers, whether employing pure ethylene oxide gas or a mixture of ethylene oxide with another gas, have the potential to cause a serious local environmental hazard. Careful consideration of ethylene oxide sterilizers is recommended if the equipment is to be operated safely.

The efficacy and/or efficiency of the ethylene oxide sterilization process can be affected by the physical condition of goods (temperature and humidity) immediately prior to being loaded into the sterilizer.

The efficacy of the process is also affected by the packaging used to wrap goods for sterilization. Suitable packaging materials and methods for the validation of novel packaging materials are described in the series of EN 868.

The safe use of products which have been sterilized by ethylene oxide can depend upon the adequate removal of residual ethylene oxide (and its reaction products) after the products are removed from the sterilizer. Appropriate procedures for the assessment are described in EN ISO 10993-7.

This standard has been prepared on the basis that every individual sterilizer will be subject to functional performance tests. Unless otherwise stated in this standard, compliance with the performance requirements is checked by visual inspection or direct measurement.

The test methods and requirements of this standard are equally applicable for assessing the functional performance of the sterilizer throughout its life.

Users of this European standard are advised to consider the desirability of third party certification for product conformity with this European standard, based on testing and continuing surveillance which can be coupled with surveillance of a supplier's quality system in accordance with EN ISO 9001.

Alternatively, users of this European standard can wish to consider the desirability of assessment and registration of a supplier's quality systems in accordance with EN ISO 9001 by a third party certification body.

1 Scope

1.1 This European standard specifies the minimum performance requirements and test methods of two types of sterilizers employing ethylene oxide gas as the sterilant, either as a pure gas or in admixture with other gases (whether supplied ready mixed or mixed at the point of use) in a temporarily sealed chamber.

These sterilizers are intended to be used for medical, dental, pharmaceutical, veterinary and industrial or related purposes. The two types of sterilizers have been designated Type A and Type B respectively using the following criteria:

— Type A sterilizers are capable of being programmed by the user;

— Type B sterilizers are of limited size and provided with one or more pre-set operating cycles which cannot be varied by the user.

The clauses of this standard apply to both types of sterilizer unless it is specifically indicated within the clause that it applies only to one of the types in particular.

1.2 This standard includes minimum performance and construction requirements for sterilizers working above or below atmospheric pressure:

— To ensure that the process is capable of being used to sterilize medical products;

— For the equipment and controls necessary to permit validation and monitoring of the sterilization process.

1.3 This standard does not specify those tests which are necessary to determine the probability of a processed product being sterile, nor the routine quality control tests required prior to release of sterile product. These topics are addressed in EN 550.

1.4 This standard does not specify the procedures and equipment which can be used to improve the efficacy and/or efficiency of the process before or after the sterilization cycle.

1.5 Considerations of operator safety are addressed in EN 61010-1: A2 and IEC 1010-2-042.

1.6 This standard is applicable when:

a) specified in a contract for supply of an ethylene oxide sterilizer;

or,

b) a sterilizer manufacturer declares compliance when intending to supply an ethylene oxide sterilizer.

This standard is not intended as a checklist for suitability of an existing ethylene oxide sterilizer when assessing compliance with EN 550.

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*

EN 866-2, *Biological systems for testing sterilizers and sterilization processes – Part 2: Particular system for use in ethylene oxide sterilizers*

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized – Part 1: General requirements and test methods*

prEN 868-4, *Packaging materials for sterilization of wrapped goods – Part 4: Paper bags – Requirements and tests*

prEN 868-5, *Packaging materials for sterilization of wrapped goods – Part 5: Heat-sealable pouches and reel material of paper and plastic film construction – Requirements and tests*

EN 50081-1, *Electromagnetic compatibility – Generic Emission standard – Part 1: residential, commercial and light industry*

EN 50081-2, *Electromagnetic compatibility – Generic Emission standard – Part 2: Industrial environment*

EN 50082-1, *Electromagnetic compatibility – Generic immunity standard – Part 1: residential, commercial and light industry*

EN 50082-2, *Electromagnetic compatibility – Generic immunity standard – Part 2: Industrial environment*

EN 60584-2, *Thermocouples – Part 2: Tolerances (IEC 584-2:1982 + A1: 1989)*

EN 60651:1994, *Sound level meters (IEC 651:1979 + A1: 1993)*

EN 60751 + A2, *Industrial platinum resistance thermometer sensors (IEC 751: 1983 + A2: 1995)*

EN 60804:1994, *Integrating-averaging sound level meters (IEC 804:1985 + A1:1989)*

EN 61010-1+ A2, *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (IEC 1010-1:1990 + A1: 1992, modified + A2:1995)*

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)*

IEC 73, *Basic and safety principles for man-machine interface, marking and identification – Coding principles for indication devices and actuators*

IEC 1010-2-042, *Safety requirements for electrical equipment for measurement, control and laboratory use – Particular requirements for autoclaves and sterilizers using toxic gas for the treatment for medical materials, and for laboratory processes*

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

ISO 6780, *General-purpose flat pallets for through transit of goods – Principal dimensions and tolerances*

ISO 10012-1, *Quality assurance requirements for measuring equipment – Part 1: Metrological confirmation system for measuring equipment*

3 Definitions

〚A1〛 For the purposes of this document, the following terms and definitions apply. 〚A1〛

NOTE Where defined terms appear in the text of this standard, an alternative type face is used.

3.1
aeration
a part or parts of the *sterilization process* in which defined conditions are used such that ethylene oxide and its reaction products are desorbed from the *medical device*, and which can be performed within the *sterilizer* (see 3.18 *flushing stage*), within a separate *room* or *chamber* (see 3.13 *degassing*), or by a combination of the two

3.2
air admission stage
the stage beginning with the attainment of the pre-set pressure on the last evacuation of the *flushing stage* or *sterilant removal stage* when filtered air is admitted to allow the chamber pressure to equilibrate with ambient pressure

3.3
air removal
removal of air from the *sterilizer chamber* and *sterilization load* sufficient to achieve validated sterilization conditions

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

3.5
biological indicator
an *inoculated carrier* contained within its primary pack ready for use [EN 866-1]