Irish Standard
I.S. EN 1422:2014

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

I.S. EN 1422:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:	*Published:*
EN 1422:2014	2014-05-21

This document was published under the authority of the NSAI and comes into effect on:	ICS number:
2014-06-07	11.080.10
	NOTE: If blank see CEN/CENELEC cover page

NSAI	T +353 1 807 3800	Sales:
1 Swift Square,	F +353 1 807 3838	T +353 1 857 6730
Northwood, Santry	E standards@nsai.ie	F +353 1 857 6729
Dublin 9	W NSAI.ie	W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1422

May 2014

ICS 11.080.10

Supersedes EN 1422:1997+A1:2009

English Version

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

Stérilisateurs à usage médical - Stérilisateurs à l'oxyde d'éthylène - Exigences et méthodes d'essai

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

This European Standard was approved by CEN on 17 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.

CEN members are the national standards bodies of 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 United Kingdom.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword

This document (EN 1422:2014) 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 May 2017.

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 1422:1997+A1:2009.

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.

For relationship with EU Directive, 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 and ZA are for information only.

The standard is a full technical revision of the previous version. The following amendments have been made in comparison with EN 1422:1997+A1:2009:

— new specification of the scope of the standard, e.g. explicit exclusion of sterilizers which employ the injection of EO or mixtures containing EO directly into packages or into a flexible chamber and removal of different types A and B of EO-sterilizers ;

— normative references have been updated;

— layout of the standard brought in line with the standard for LTSF-sterilization (EN 14180);

— the additional requirements from the machinery directive, introduced by the revision of the medical devices directive 2007/47/EC have been addressed (see revised Annex ZA), i.e. update of technical requirements and Tables ZA.1 and ZA.2;

— requirements have been rephrased to be performance requirements instead of design requirements;

— addition of an environmental checklist;

— Annex B has been thoroughly revised and Annex D has been deleted.

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

Ethylene oxide (EO) sterilizers employing EO gas as the sterilant, either as a pure gas or in admixture with other gases, are primarily used for the sterilization of heat labile material or product.

The EO-sterilizer specified in this European standard can be used for medical, dental, pharmaceutical veterinary and industrial or related purposes.

The tests described in this European Standard are reference tests intended for use in demonstrating conformity with the performance requirements specified in this European Standard. They can be used in type tests, works tests, in validation and re-validation tests, or in periodic and routine tests carried out by the user.

Validation and routine control of sterilization processes are essential to ensure their efficacy. This European Standard does not cover validation and routine control of EO processes (see prEN ISO 11135:2012). EO is a highly reactive chemical which can present a toxic, flammable or explosive hazard if incorrectly handled (see Annex E).

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.

Planning and design of products complying with 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 E of this standard.

By performing tests concurrently and/or in a logical sequence, the total number of tests carried out and waste arising from such tests, is reduced. As a result the burden on the environment can be reduced (see also Annex E).

1 Scope

This European Standard specifies the requirements and the relevant tests for automatically controlled sterilizers employing ethylene oxide (EO) gas as the sterilant, either as a pure gas or a mixture with other gases, being used for the sterilization of medical devices and their accessories.

This European Standard specifies requirements for ethylene oxide sterilizers (EO-sterilizers) working at super or sub-atmospheric pressure for:

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

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

The test loads described in this European Standard are selected to represent a number of loads for the evaluation of the performance of EO sterilizers for medical devices. However, specific loads may require the use of other test loads.

This European 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 prEN ISO 11135:2012.

This European Standard does not specify requirements for occupational safety associated with the design and operation of EO sterilization facilities.

NOTE 1 For further information on safety, see examples in the Bibliography. National or regional regulations can exist.

This European Standard does not cover sterilizers which employ the injection of EO or mixtures containing EO directly into packages or into a flexible chamber.

NOTE 2 See EN ISO 14937.

This European Standard is not intended as a checklist for suitability of an existing EO sterilizer when assessing compliance with prEN ISO 11135:2012. This standard is not intended to be applied retrospectively.

This European Standard does not cover analytical methods for determining levels of residual EO and/or its reaction products.

NOTE 3 For further information see ISO 10993-7.

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 868-4, *Packaging for terminally sterilized medical devices - Part 4: Paper bags - Requirements and test methods*

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*