

**Bioloogilised süsteemid sterilisaatorite ja  
sterilisatsiooniprotsesside katsetamiseks. Osa 2:  
Spetsiaalsüsteemid kasutamiseks  
etüleenoksiidsterilisaatorites**

Sterilization of health care products - Biological indicators -  
Part 2: Biological indicators for ethylene oxide sterilization  
processes

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11138-2:2009 sisaldab Euroopa standardi EN ISO 11138-2:2009 ingliskeelset teksti.

Standard on kinnitatud Eesti Standardikeskuse 31.07.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.

Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 06.05.2009.

Standard on kättesaadav Eesti standardiorganisatsioonist.

This Estonian standard EVS-EN ISO 11138-2:2009 consists of the English text of the European standard EN ISO 11138-2:2009.

This standard is ratified with the order of Estonian Centre for Standardisation dated 31.07.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.

Date of Availability of the European standard text 06.05.2009.

The standard is available from Estonian standardisation organisation.

ICS 11.080.01

**Võtmesõnad:** bioloogiline proov, bioloogilised indikaatorid, etüleenoksiid, meditsiiniaparatuur, sterilisaatorid, steriliseerimine, tehnilised andmed

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English Version

**Sterilization of health care products - Biological indicators - Part  
2: Biological indicators for ethylene oxide sterilization processes  
(ISO 11138-2:2006)**

Stérilisation des produits de santé - Indicateurs biologiques  
- Partie 2: Indicateurs biologiques pour la stérilisation à  
l'oxyde d'éthylène (ISO 11138-2:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge -  
Biologische Indikatoren - Teil 2: Biologische Indikatoren für  
Sterilisationsverfahren mit Ethylenoxid (ISO 11138-2:2006)

This European Standard was approved by CEN on 19 April 2009.

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 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 Management Centre has the same status as the official versions.

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

**Management Centre: Avenue Marnix 17, B-1000 Brussels**

## Foreword

The text of ISO 11138-2:2006 has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11138-2:2009 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.

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 ISO 11138-2:2006.

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 EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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 the United Kingdom.

### Endorsement notice

The text of ISO 11138-2:2006 has been approved by CEN as a EN ISO 11138-2:2009 without any modification.

## Annex ZA (informative)

### Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

**Table ZA – Correspondence between this European Standard and Directive 93/42/EEC on medical devices**

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	5, 13	The requirements of ISO 11138-1 apply
5.1	7.2, 7.3	
7	7.3	
9	10.1	

**WARNING** – Other requirements and other EU-directives may be applicable to the product(s) falling within the scope of the standard."

## Introduction

ISO 11138-1 specifies production, labelling, test methods and performance requirements for the manufacture of biological indicators including inoculated carriers and suspensions intended for use in validation and monitoring of sterilization processes. This part of ISO 11138 gives specific requirements for those biological indicators intended for use in ethylene oxide sterilization processes.

The intent of providing requirements in the ISO 11138 series of International Standards is to provide general requirements and requirements for test methods. This series of International Standards represents the current “state-of-the-art” according to the experts representing manufacturers, users and regulatory authorities involved in developing the standard. The intent is not to promote the use of biological indicators where such use is not advised, but rather to provide common requirements for the production of those biological indicators that are known to be in use today.

Standards exist providing requirements for the validation and control of ethylene oxide sterilization (see ISO 11135).

NOTE Some countries or regions may have published other standards covering requirements for sterilization or biological indicators.

Advice on selection, use and interpretation of results when using biological indicators can be found in ISO 14161.

# **Sterilization of health care products — Biological indicators —**

## **Part 2:**

# **Biological indicators for ethylene oxide sterilization processes**

## **1 Scope**

This part of ISO 11138 provides specific requirements for test organisms, suspensions, inoculated carriers, biological indicators and test methods intended for use in assessing the performance of sterilizers and sterilization processes employing ethylene oxide gas as the sterilizing agent, either as pure ethylene oxide gas or mixtures of this gas with diluent gases, at sterilizing temperatures within the range of 29 °C to 65 °C.

NOTE 1 Requirements for validation and control of ethylene oxide sterilization processes are provided by ISO 11135.

NOTE 2 National or regional regulations could provide requirements for work place safety.

## **2 Normative references**

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.

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

ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*