

# Sterilization of health care products — Biological indicators

## Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)

ICS 11.080.01

# National foreword

This British Standard is the UK implementation of EN ISO 11138-2:2009. It is identical to ISO 11138-2:2006. It supersedes BS EN ISO 11138-2:2006 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

**Compliance with a British Standard cannot confer immunity from legal obligations.**

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## Amendments/corrigenda issued since publication

| Date | Comments |
|------|----------|
|      |          |
|      |          |
|      |          |
|      |          |

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.

CEN members are the national standards bodies of 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.



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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."