SLOVENSKI STANDARD
kSIST prEN ISO 11138-2:2009

01-marec-2009

Sterilizacija izdelkov za zdravstveno nego - Biološki indikatorji - 2. del: Biološki indikatorji za sterilizacijske postopke z etilenoksidom (ISO 11138-2:2006)

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

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

Ta slovenski standard je istoveten z: **prEN ISO 11138-2**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

kSIST prEN ISO 11138-2:2009 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
prEN ISO 11138-2

December 2008

ICS 11.080.01

Will supersede EN ISO 11138-2:2006

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 draft European Standard is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 102.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. prEN ISO 11138-2:2008: E

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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 prEN ISO 11138-2:2008 by Technical Committee CEN/TC 102 “Sterilizers for medical purposes” the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document will supersede 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.

Endorsement notice

The text of ISO 11138-2:2006 has been approved by CEN as a prEN ISO 11138-2:2008 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."

INTERNATIONAL STANDARD

ISO 11138-2

Second edition
2006-07-01

Sterilization of health care products — Biological indicators —

Part 2: Biological indicators for ethylene oxide sterilization processes

Stérilisation des produits de santé — Indicateurs biologiques —

Partie 2: Indicateurs biologiques pour la stérilisation à l'oxyde d'éthylène

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