TERVISHOIUTOODETE STERILISEERIMINE. KEEMILISED NÄITAJAD. OSA 1: ÜLDISED NÕUDED

Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2014)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11140-1:2014 sisaldab Euroopa standardi EN ISO 11140-1:2014 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11140-1:2014 consists of the English text of the European standard EN ISO 11140-1:2014.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 12.11.2014.	Date of Availability of the European standard is 12.11.2014.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.080.01

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11140-1

November 2014

ICS 11.080.01

Supersedes EN ISO 11140-1:2009

English Version

Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2014)

Stérilisation des produits de santé - Indicateurs chimiques - Partie 1: Exigences générales (ISO 11140-1:2014)

Sterilisation von Produkten für die Gesundheitsfürsorge - Chemische Indikatoren - Teil 1: Allgemeine Anforderungen (ISO 11140-1:2014)

This European Standard was approved by CEN on 23 August 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.

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COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Ref. No. EN ISO 11140-1:2014 E

Foreword

This document (EN ISO 11140-1:2014) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with 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 May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.

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 11140-1:2009.

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(s).

For relationship with EU Directive(s), 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, 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.

Endorsement notice

The text of ISO 11140-1:2014 has been approved by CEN as EN ISO 11140-1:2014 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC on medical devices

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/EC on medical devices.

Once this standard is cited in the Official Journal of the European Union 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.1 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.1 — Correspondence between this European Standard and Directive 93/42/EC on medical devices

Clause(s)/sub-clause(s) of this EN ISO 11140-1	Essential Requirements (ERs) of Directive 93/42/EC	Qualifying remarks/Notes
5.9 6.2.2 6.4.2 7.2	7.2	release of toxic substances transfer type 1 transfer type. 3 – 6 test procedure
5.8 g) 5.8 h) 6.2.2	7.3, 1st part	Interfering substances Safety precautions required during and/or after use Bleed and offset
4.1; 4.2; 5; 6.1; 6.2; 7; 8	8.7	type 1 indicator
5.8	13.1	Instructions for use
5.6, 5.7	13.2	Symbols
5.4, 5.6, 5.7, 5.8 i), 5.8 k) 4 5.2	13.3 a), b)	Labelling Classification of indicators Critical variables and stated values
5.8 j)	13.3 c)	Labelling
5.4, 5.6, 5.7, 5.8 i), 5.8 k) 4 5.2	13.3 d)	Labelling Classification of indicators Critical variables and stated values
5.8 j)	13.3 e), f), g), h)	Labelling, expiry date.

Clause(s)/sub-clause(s) of this prEN ISO 11140-1	Essential Requirements (ERs) of Directive 93/42/EC	Qualifying remarks/Notes
5.8 e) 5.8 g)	13.3 i)	Storage Interfering substances
5.8	13.3 j)	Instructions for use
5.8 h)	13.3 k)	Safety precautions
5.4, 5.6, 5.7, 5.8 i), 5.8 k) 4 5.2	13.3 l)	Labelling Classification of indicators Critical variables and stated values
5.8 j)	13.3 m), n)	Labelling
5.4	13.4	Marking
5.8	13.6 a)	Marking
5.8	13.6 b)	Marking
5.8 h) 5.9	13.6 e)	Instructions after use Toxicity declaration
5.8 g)	13.6 f)	Interfering substances
5.8 h) 5.9	13.6 g), h), j), k), l), m), n), o), p)	Instructions after use Toxicity declaration

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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