SLOVENSKI STANDARD
SIST EN ISO 11140-1:2015

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Nadomešča:
SIST EN ISO 11140-1:2009

Sterilizacija izdelkov za zdravstveno nego - Kemijski indikatorji - 1. del: Splošne zahteve (ISO 11140-1:2014)

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

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

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

Ta slovenski standard je istoveten z: **EN ISO 11140-1:2014**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 11140-1:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11140-1

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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.

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

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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 prEN ISO 11140-1	Essential Requirements (ERs) of Directive 93/42/EC	Qualifying remarks/Notes
5.9	7.2	release of toxic substances
6.2.2		transfer type 1
6.4.2		transfer type: 3 – 6
7.2		test procedure
5.8 g)	7.3, 1st part	Interfering substances
5.8 h)		Safety precautions required during and/or after use
6.2.2		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)	13.3 a), b)	Labelling
4		Classification of indicators
5.2		Critical variables and stated values
5.8 j)	13.3 c)	Labelling
5.4, 5.6, 5.7, 5.8 i), 5.8 k)	13.3 d)	Labelling
4		Classification of indicators
5.2		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.

INTERNATIONAL STANDARD

ISO 11140-1

Third edition
2014-11-01

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

Stérilisation des produits de santé — Indicateurs chimiques —

Partie 1: Exigences générales

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 198, *Sterilization of health care products*.

This third edition cancels and replaces the second edition (ISO 11140-1:2005), which has been technically revised.

ISO 11140 consists of the following parts, under the general title *Sterilization of health care products — Chemical indicators*:

— *Part 1: General requirements*

— *Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*

— *Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

— *Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

ISO 11140-2 has been withdrawn and replaced by ISO 18472.