



SLOVENSKI STANDARD SIST EN ISO 11140-1:2015

01-marec-2015

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11140-1:2015](https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015)

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>

EUROPEAN STANDARD

EN ISO 11140-1

NORME EUROPÉENNE

EUROPÄISCHE NORM

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.

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.

[SIST EN ISO 11140-1:2015](https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015)

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>



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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Contents	Page
Foreword	3
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EC on medical devices	4

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11140-1:2015](https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015)
<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>

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.

[SIST EN ISO 11140-1:2015](https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c475/sist-en-iso-11140-1-2015)

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c475/sist-en-iso-11140-1-2015>

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, 1 st 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)	13.3 i)	Storage
5.8 g)		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)	13.3 l)	Labelling
4		Classification of indicators
5.2		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)	13.6 e)	Instructions after use
5.9		Toxicity declaration
5.8 g)	13.6 f)	Interfering substances
5.8 h)	13.6 g), h), j), k), l), m), n), o), p)	Instructions after use
5.9		Toxicity declaration

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

[SIST EN ISO 11140-1:2015](https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015)

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11140-1:2015](https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015)

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>

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
iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11140-1:2015

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>



Reference number
ISO 11140-1:2014(E)

© ISO 2014

iTeh STANDARD PREVIEW (standards.iteh.ai)

SIST EN ISO 11140-1:2015

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2014

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Categorization	4
4.1 General	4
4.2 Type 1: process indicators	4
4.3 Type 2: indicators for use in specific tests	5
4.4 Type 3: single critical process variable indicators	5
4.5 Type 4: multicritical process variable indicators	5
4.6 Type 5: integrating indicators	5
4.7 Type 6: emulating indicators	5
5 General requirements	5
6 Performance requirements	8
6.1 General	8
6.2 Type 1 indicators	9
6.3 Type 2 indicators	9
6.4 Types 3, 4, 5 and 6 indicators	9
7 Test methods	9
7.1 General	9
7.2 Off-set (transference)	9
7.3 Procedure — Steam indicators	9
7.4 Procedure — Dry heat indicators	10
7.5 Procedure — EO indicators	10
7.6 Procedure — Low temperature steam and formaldehyde indicators	11
7.7 Procedure — Vaporized hydrogen peroxide indicators	11
8 Additional requirements for process (Type 1) indicators	12
8.1 Process indicators printed or applied on to packaging material	12
8.2 Process indicators for steam sterilization processes	12
8.3 Process indicators for dry heat sterilization processes	12
8.4 Process indicators for ethylene oxide sterilization processes	13
8.5 Process indicators for radiation sterilization processes	13
8.6 Process indicators for low temperature steam and formaldehyde sterilization processes	14
8.7 Process indicators for vaporized hydrogen peroxide sterilization processes	14
9 Additional requirements for single critical process variable (Type 3) indicators	15
10 Additional requirements for multicritical process variable (Type 4) indicators	15
11 Additional requirements for steam integrating (Type 5) indicators	16
12 Additional requirements for ethylene oxide integrating (Type 5) indicators	17
13 Additional requirements for emulating (Type 6) indicators	17
Annex A (normative) Method for demonstrating shelf-life of the product	19
Annex B (informative) Examples of testing indicators	20
Annex C (informative) Rationale for the requirements for integrating indicators and the link to the requirements for biological indicators specified in ISO 11138 (all parts) and microbial inactivation	22
Annex D (informative) Rationale for the liquid-phase test method for low temperature steam and	

ISO 11140-1:2014(E)

formaldehyde indicators	29
Annex E (informative) Relationship of indicator and indicator system components	30
Bibliography	31

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SIST EN ISO 11140-1:2015](https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015)

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received. www.iso.org/patents

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.

<https://standards.iteh.ai/catalog/standards/sist/77258d58-61af-4d33-a914-38d91a1c47f5/sist-en-iso-11140-1-2015>

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.