ICS 11.080.01 SLOVENSKÁ TECHNICKÁ NORMA Máj 2015

STN	**Sterilizácia výrobkov zdravotnej starostlivosti. Chemické indikátory. Časť 1: Všeobecné požiadavky (ISO 11140-1: 2014).**	**STN EN ISO 11140-1** 85 6541

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 04/15

Obsahuje: EN ISO 11140-1:2014, ISO 11140-1:2014

Oznámením tejto normy sa ruší
STN EN ISO 11140-1 (85 6541) z novembra 2009

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EUROPEAN STANDARD

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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.

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

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

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

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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of an identical text or by endorsement, at the latest by May 2015, and conflicting national standards shall be withdrawn at the latest by May 2015.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 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 EN 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.

STN 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

Reference number
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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

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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

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.

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.

Introduction

This part of ISO 11140 specifies performance requirements and/or test methods for chemical indicators intended for use with sterilization processes employing steam, dry heat, ethylene oxide, γ or β radiation, low temperature steam and formaldehyde or vaporized hydrogen peroxide.

Additional requirements for indicators intended for use with other sterilization methods (e.g. other forms of moist heat sterilization) are not specifically provided in this part of ISO 11140; however, the general requirements will apply.

The requirements for specific test indicators (e.g. Bowie-Dick test indicators and indicator systems) are covered in other parts of ISO 11140.

Standards for sterilizers and for the validation and process control of sterilization describe performance tests for sterilizers and methods of validation and routine control, respectively.

This part of ISO 11140 is intended for manufacturers of chemical indicators and specifies the general requirements for chemical indicators. The categorization structure for chemical indicators is used solely to denote the characteristics and intended use of each type of indicator when used as specified by the manufacturer. This categorization has no hierarchical significance. The chemical indicators described in this part of ISO 11140 are categorized into six types. The chemical indicators within each of these categorizations are further subdivided by the sterilization process for which they are designed to be used. This part of ISO 11140 defines the requirements for Type 1 and Types 3 to 6. In subsequent parts of ISO 11140, the requirements for Type 2 indicators are categorized by their intended use. The use of the indicators and indicator systems, specified in this part of ISO 11140, is described in for example the ISO 11135, the ISO 17665- series, ISO 15882, EN 285, and EN 13060.

Resistometers are used to characterize the performance of the chemical indicators described in this part of ISO 11140, with the exception of Type 2 indicators. Requirements for resistometers are specified in ISO 18472. Resistometers differ from sterilizers. As sterilizers cannot duplicate resistometer conditions they should not be used to test the performance of chemical indicators. Sterilizers from different manufacturers and of different ages have significantly different cycle profiles; for example, prolonged preconditioning phases. Resistometers allow for precise control of the specific test cycle sequences in order to study the effect of process parameters on indicator performance under controlled, repeatable conditions. Guidance on the selection, use and interpretation of the results of chemical indicators is given in ISO 15882. Users of chemical indicators are expected to make reference to this part of ISO 11140.

INTERNATIONAL STANDARD **ISO 11140-1:2014(E)**

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

WARNING — The use of this part of ISO 11140 can involve hazardous materials, operations and equipment. This part of ISO 11140 does not purport to address all of the safety problems associated with their use. It is the responsibility of the user of this part of ISO 11140 to determine the applicability of national or regional regulatory requirements and to establish appropriate occupational health and safety practices prior to use of any hazardous materials, operations and/or equipment.

1 Scope

This part of ISO 11140 specifies general requirements and test methods for indicators that show exposure to sterilization processes by means of physical and/or chemical change of substances, and which are used to monitor the attainment of one or more of the process parameter(s) specified for a sterilization process. They are not dependent for their action on the presence or absence of a living organism.

NOTE 1 Biological test systems are regarded as those test systems which are dependent for their interpretation on the demonstration of the viability of an organism. Test systems of this type are considered in the ISO 11138-series for biological indicators (BIs).

The requirements and test methods of this part of ISO 11140 apply to all indicators specified in subsequent parts of ISO 11140, unless the requirement is modified or added to by a subsequent part, in which case the requirement of that particular part will apply.

Relevant test equipment is described in ISO 18472.

NOTE 2 Additional requirements for specific test indicators/indicator systems (Type 2 indicators) are given in ISO 11140-3, ISO 11140-4 and ISO 11140-5.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601:2004, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11135:2014, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2:2013, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

ISO 11137-3:2006, *Sterilization of health care products — Radiation — Part 3: Guidance on dosimetric aspects*

ISO 11138-1:2006, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-2:2006, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3:2006, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11138-4:2006, *Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes*

ISO 11138-5:2006, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

ISO 11140-3:2007, *Sterilization of health care products — Chemical indicators — Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test*

ISO 11140-4:2007, *Sterilization of health care products — Chemical indicators — Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration*

ISO 11140-5:2007, *Sterilization of health care products — Chemical indicators — Part 5: Class 2 indicators for Bowie and Dick-type air removal tests*

ISO 17665-1:2006, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO/TS 17665-2:2009, *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1*

ISO/TS 17665-3:2013, *Sterilization of health care products — Moist heat — Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization*

ISO 18472:2006, *Sterilization of health care products — Biological and chemical indicators — Test equipment*