



NSAI
Standards

Irish Standard
I.S. EN ISO 11140-1:2014

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

I.S. EN ISO 11140-1:2014

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation — recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:

EN ISO 11140-1:2014

Published:

2014-11-12

This document was published under the authority of the NSAI and comes into effect on:

2014-12-01

ICS number:

11.080.01

NOTE: If blank see CEN/CENELEC cover page

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann



Correction Notice

Reference: EN ISO 11140-1:2014

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

Work Item: 00102120

Brussels, 2014-12-10

Please include the following minor editorial correction(s) in the document related to:

the following language version(s) :

- English
- French
- German

for the following procedure :

- PQ/UQ
- Enquiry
- 2nd Enquiry
- Parallel Enquiry
- 2nd Parallel Enquiry
- Formal Vote
- 2nd Formal Vote
- Parallel Formal Vote
- 2nd Parallel Formal Vote
- UAP
- TC Approval
- 2nd TC Approval
- Publication
- Parallel Publication

It has been brought to our attention that this document, issued on 2014-11-12, requires modification.

Correction of EN ISO reference in Annex ZA, Table ZA.1, 1st column (deletion of "pr").

Please find enclosed the updated English and French versions.

We apologise for any inconvenience this may cause.

This page is intentionally left BLANK.

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.



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

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

EN ISO 11140-1:2014 (E)

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

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	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)
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 EN 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

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

This page is intentionally left blank

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
ISO 11140-1:2014(E)

© ISO 2014

ISO 11140-1:2014(E)



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

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.

ISO 11140-1:2014(E)

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.

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*

This is a free preview. Purchase the entire publication at the link below:

[Product Page](#)

-
- [Looking for additional Standards? Visit Intertek Inform Infostore](#)
 - [Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation](#)
-