

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

The European Standard EN ISO 11140-1:2005 has the status of a
British Standard

ICS 11.080.01

National foreword

This British Standard is the official English language version of EN ISO 11140-1:2005. It is identical with ISO 11140-1:2005. It supersedes BS EN 867-1:1997 and BS EN 867-2:1997 which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN ISO title page, the EN ISO foreword page, the ISO title page, pages ii to v, a blank page, pages 1 to 16, an inside back cover and a back cover.

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English Version

Sterilization of health care products - Chemical indicators - Part
1: General requirements (ISO 11140-1:2005)

Stérilisation des produits de santé - Indicateurs chimiques -
Partie 1: Exigences générales (ISO 11140-1:2005)

Sterilisation von Produkten für die Gesundheitsfürsorge -
Chemische Indikatoren - Teil 1: Allgemeine Anforderungen
(ISO 11140-1:2005)

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Foreword

This document (EN ISO 11140-1:2005) 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of an identical text or by endorsement, at the latest by January 2006, and conflicting national standards shall be withdrawn at the latest by January 2006.

This document supersedes EN 867-1:1997 and EN 867-2:1997.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 11140-1:2005 has been approved by CEN as EN ISO 11140-1:2005 without any modifications.

NOTE Normative references to International Standards are listed in Annex ZA (normative).

INTERNATIONAL STANDARD

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Sterilization of health care products — Chemical indicators —

Part 1: General requirements

*Stérilisation des produits de santé — Indicateurs chimiques —
Partie 1: Exigences générales*



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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11140-1 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This second edition cancels and replaces the first edition (ISO 11140-1:1995 and ISO 11140-1:1995/Amd.1:1998), 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 2: Test equipment and methods*
- *Part 3: Class 2 indicators for steam penetration test sheets*
- *Part 4: Class 2 indicators for steam penetration test packs*
- *Part 5: Class 2 indicators for air removal test sheets and packs*

NOTE ISO 11140-2 is to be replaced by ISO 18472, *Sterilization of health care products — Biological and chemical indicators — Test equipment*.

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, steam-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) 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. Subsequent parts of this International Standard specify the particular requirements for chemical indicators for particular applications and for defined tests of particular sterilization processes used in health care, including industry. The use of the indicators specified in this part of ISO 11140 are described in ISO 15882, EN 285, ISO 11135 and ISO 17665.

Resistometers (see ISO 18472) are used to characterize the performance of the chemical indicators described in this part of ISO 11140. Resistometers allow for precise variation of the specific test conditions and cycle sequences in order to produce controlled physical studies. Resistometers differ from conventional sterilizers; therefore, if conventional sterilizers are used to attempt to duplicate resistometer conditions, erroneous and/or misleading results may occur.

Sterilization of health care products — Chemical indicators —

Part 1: General requirements

WARNING — The use of this part of ISO 11140 may involve hazardous materials, operations and equipment. This part of ISO 11140 does not purport to address to all the safety problems associated with its use. It is the responsibility of the user of this part of ISO 11140 to establish appropriate safety and health practise and determine the applicability of regulatory limitations prior to use.

1 Scope

1.1 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 variables required for a sterilization process. They are not dependent for their action on the presence or absence of a living organism.

NOTE Biological test systems are regarded as those tests 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).

1.2 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 Additional requirements for specific test indicators (Class 2 indicators) are given in ISO 11140-3, ISO 11140-4 and ISO 11140-5.

2 Normative references

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

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

ISO 11138 (all parts), *Sterilization of health care products — Biological indicator systems*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 18472¹⁾, *Sterilization of health care products — Biological and chemical indicators — Test equipment*

1) To be published.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

bleed

lateral migration of the indicator agent beyond the margins within which the indicator agent was applied

3.2

critical variable

parameters identified as being essential to the sterilization process (and requiring monitoring)

3.3

endpoint

point of the observed change as defined by the manufacturer occurring after the indicator has been exposed to specified stated values

3.4

graduated response

progressive observable change occurring on exposure to one or more process variables allowing assessment of the level achieved

3.5

indicator

combination of the indicator agent and its substrate in the final form in which it is intended to be used (see Annex E)

NOTE An indicator system in combination with a specific test load is also termed an indicator.

3.6

indicator agent/indicator reagent

active substance(s) or combination of substances (see Annex E)

3.7

indicator system

combination of the indicator agent and its substrate subsequently intended to be used in combination with a specific test load

3.8

off-set

transfer of indicator agent to a material in intimate contact with the surface of the indicator

3.9

parameter

specified value for a process variable

3.10

penetration

migration of the indicator agent through the substrate to the surface opposite the one to which the indicator agent was applied

3.11

saturated steam

water vapour in a state of equilibrium between condensation and evaporation