



**SLOVENSKI STANDARD**  
**SIST EN ISO 11140-1:2005**  
**01-november-2005**

**BUXca Yý U.**  
**SIST EN 867-1:2000**  
**SIST EN 867-2:2000**

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**Sterilizacija izdelkov za zdravstveno nego – Kemijski indikatorji – 1. del: Splošne zahteve (ISO 11140-1:2005)**

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

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

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

**Ta slovenski standard je istoveten z: EN ISO 11140-1:2005**

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**ICS:**

11.080.01 Sterilizacija in dezinfekcija na splošno Sterilization and disinfection in general

**SIST EN ISO 11140-1:2005 en**

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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)

This European Standard was approved by CEN on 14 July 2005.

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of 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.

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

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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**

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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).

**Annex ZA**  
(normative)

**Normative references to international publications  
with their relevant European publications**

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN</u>	<u>Year</u>
ISO 8601	1988	Data elements and interchange formats - Information interchange - Representation of dates and times	EN 28601	1992

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**ANNEX ZA**  
(informative)

**Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC**

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 EEC.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard given in Table ZA. 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.

**WARNING:** Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this 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,  $\gamma$  or  $\beta$  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.

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