



SLOVENSKI STANDARD SIST EN ISO 15882:2003

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Sterilizacija izdelkov za zdravstveno oskrbo – Kemijski indikatorji - Navodilo za izbiro, uporabo in predstavitev rezultatov (ISO 15882:2003)

Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results (ISO 15882:2003)

Sterilisation von Produkten für die Gesundheitsfürsorge - Chemische Indikatoren - Leitfaden für die Auswahl, Verwendung und Interpretation von Ergebnissen (ISO 15882:2003)

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Stérilisation des produits de santé - Indicateurs chimiques - Lignes directrices pour le choix, l'emploi et l'interprétation des résultats (ISO 15882:2003)

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11.080.01 Sterilizacija in dezinfekcija na splošno Sterilization and disinfection in general

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 15882

March 2003

ICS 11.080.01

English version

**Sterilization of health care products - Chemical indicators -
Guidance for selection, use and interpretation of results (ISO
15882:2003)**

Stérilisation des produits de santé - Indicateurs chimiques -
Lignes directrices pour le choix, l'emploi et l'interprétation
des résultats (ISO 15882:2003)

Sterilisation von Produkten für die Gesundheitsfürsorge -
Chemische Indikatoren - Leitfaden für die Auswahl,
Verwendung und Interpretation von Ergebnissen (ISO
15882:2003)

This European Standard was approved by CEN on 11 March 2003.

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 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 Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
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EN ISO 15882:2003 (E)

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Foreword

This document (EN ISO 15882:2003) 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 September 2003, and conflicting national standards shall be withdrawn at the latest by September 2003.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 15882:2003 has been approved by CEN as EN ISO 15882:2003 without any modifications.

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INTERNATIONAL STANDARD

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Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results

*Stérilisation des produits de santé — Indicateurs chimiques — Lignes
directrices pour le choix, l'emploi et l'interprétation des résultats*

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ISO 15882:2003(E)**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 15882 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

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Introduction

Performance requirements for manufacturers of chemical indicators are contained in the ISO 11140 series. This International Standard provides guidance regarding the selection, use and interpretation of results of chemical indicators used to monitor sterilization processes employing steam, ethylene oxide, γ - or β -radiation, steam-formaldehyde, or dry heat as documented in ISO 11140-1:1995 (amended 1998). The procedures described in this International Standard are of a general nature and do not, of themselves, constitute a comprehensive monitoring programme with regard to the sterilization of health care products. The intent of this International Standard is not to mandate the use of chemical indicators in a process, but to provide guidance for their proper selection and use. National standards should be consulted for information on the use of chemical indicators as well as the frequency of their use.

The complexity of modern medical technology and the wide variety of sterilization processing techniques and equipment available have made effective sterility assurance programmes more challenging than ever before. The need for convenient, inexpensive and rapid means of detecting sterilization problems has brought about the development of sterilization process monitors generally referred to as “chemical indicators”. In this International Standard, users will find guidance on selection of the correct chemical indicator for their particular sterilization process and critical parameters, e.g. the choice of an appropriate chemical indicator, as well as guidance on its appropriate use.

Harmonization of the International and European standards on chemical indicators, ISO 11140 and EN 867, is in progress.

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Sterilization of health care products — Chemical indicators — Guidance for selection, use and interpretation of results

1 Scope

This International Standard provides guidance for the selection, use and interpretation of results of chemical indicators used in process definition, validation, and routine monitoring and control of sterilization processes. This International Standard is applicable to chemical indicators for which International Standards exist (see ISO 11140 series).

This International Standard is not applicable to those processes that rely on physical removal of microorganisms, e.g. filtration.

This International Standard is not intended to apply to combination processes, for example, washer-disinfectors or flushing and steaming of pipelines.

2 Normative references

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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 11138-2:1994, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization*

ISO 11138-3:1994, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization*

ISO 11140-1, *Sterilization of health care products — Chemical Indicators — Part 1: General requirements*

3 Terms and definitions

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

3.1

endpoint

observable change specified by the manufacturer that occurs after the indicator has been exposed to certain predefined physical conditions

3.2

chemical indicator

system that reveals a change in one or more predefined process variables based on a chemical or physical change resulting from exposure to a process

3.3

critical parameter

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