SLOVENSKI STANDARD
SIST EN ISO 18472:2006

01-julij-2006

Sterilizacija izdelkov za zdravstveno nego - Biološki in kemijski indikatorji - Preskusna oprema (ISO 18472:2006)

Sterilization of health care products - Biological and chemical indicators - Test equipment (ISO 18472:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische und chemische Indikatoren - Prüfausrüstung (ISO 18472:2006)

Stérilisation des produits de santé - Indicateurs biologiques et chimiques - Appareillage d'essai (ISO 18472:2006)

Ta slovenski standard je istoveten z: **EN ISO 18472:2006**

ICS:

11.080.01	Sterilizacija in dezinfekcija na splošno	Sterilization and disinfection in general

SIST EN ISO 18472:2006 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18472

June 2006

ICS 11.080.01

English Version

Sterilization of health care products - Biological and chemical indicators - Test equipment (ISO 18472:2006)

Stérilisation des produits de santé - Indicateurs biologiques et chimiques - Appareillage d'essai (ISO 18472:2006)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische und chemische Indikatoren - Prüfausrüstung (ISO 18472:2006)

This European Standard was approved by CEN on 19 May 2006.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Ref. No. EN ISO 18472:2006: E

Foreword

This document (EN ISO 18472:2006) 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 December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 18472:2006 has been approved by CEN as EN ISO 18472:2006 without any modifications.

INTERNATIONAL STANDARD

ISO 18472

First edition
2006-06-01

Sterilization of health care products — Biological and chemical indicators — Test equipment

Stérilisation des produits de santé — Indicateurs biologiques et chimiques — Appareillage d'essai

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Contents

Page

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 18472 was prepared by Technical Committee ISO/TC 198, *Sterilization of health care products*.

This first edition of ISO 18472 partially replaces ISO 11140-2.

Introduction

To test the performance of chemical and biological indicators, specific test equipment is required. This International Standard specifies the performance requirements for the test equipment to be used in order to establish the response of chemical and biological indicators to critical process variables. This International Standard does not apply to test equipment for irradiation indicators or low temperature steam and formaldehyde indicators.

Resistometers constitute test equipment designed to create precise and repeatable sterilizing environments, allowing the evaluation of their effect on biological inactivation kinetics, chemical reactions, material degradation and product bioburden. Resistometers allow precise variation of the environmental conditions and cycle sequences in order to produce controlled physical studies. When used with the defined test methods given in ISO 11138 for biological indicators and ISO 11140 for chemical indicators, the results of these studies can be used to demonstrate conformance of biological indicators and chemical indicators to these standards.

Resistometers differ from conventional sterilizers. Instrumentation selection and control requirements for resistometers are based upon mathematical models in which rates of reaction, measurement accuracy and process control requirements are evaluated to quantify the effects induced by test equipment-controlled variables. The requirements for accurate measurement, precise control, and rapid rates of change approach limits of commercially available process control and calibration instrumentation accuracy. The measurement and control requirements often prohibit practical validation of a resistometer using procedures that might be employed in a conventional heat or chemical sterilization system. Resistometers are considered test equipment rather than sterilizers; therefore, an understanding of instrumentation and process design is critical in clarifying requirements on precision and accuracy. Practical design has to consider the following:

— achievable measurement and control;

— acceptable equipment induced variation in test results;

— economic design (utilizing tight process controls only where required);

— test method correlation with intended use;

— historical knowledge applied to test procedures and an understanding of micro-environmental physical phenomena;

— testing and analysis alternatives, when accurate quantitative determinations exceed physical measurement/control limits.

Sterilization of health care products — Biological and chemical indicators — Test equipment

1 Scope

1.1 This International Standard specifies the requirements for test equipment to be used to test chemical and biological indicators for steam, ethylene oxide, dry heat and vaporized hydrogen peroxide processes for conformity to the requirements given in ISO 11140-1 for chemical indicators, or the requirements given in the ISO 11138 series for biological indicators. This International Standard also provides informative methods useful in characterizing the performance of biological and chemical indicators for intended use and for routine quality control testing.

ISO 11138-2, ISO 11138-3, ISO 11138-4, and ISO 11140-1 require the use of resistometers specified in this International Standard, and these resistometers are used in conjunction with the test methods specified in the appropriate parts of ISO 11138 and ISO 11140.

NOTE Resistometers for formaldehyde indicators are not included in this International Standard. Test methods using laboratory apparatus for steam-formaldehyde are included in ISO 11138-5, ISO 11140-3 and ISO 11140-4.

1.2 This International Standard does not address the methods used to demonstrate compliance of biological or chemical indicators to ISO 11138 and ISO 11140, as these are covered in the appropriate parts of these standards. Indicators used with combination processes, such as washer-disinfection, are not covered by this International Standard.

NOTE Test equipment and methods necessary for ISO 11140-3, ISO 11140-4 or ISO 11140-5 are specified in those standards.

1.3 This International Standard does not address safety aspects of the test equipment because these are usually covered by specific regional, national or local regulations.

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

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

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

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