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SWEDISH STANDARDS INSTITUTE

Sterilisering av medicintekniska produkter – Biologiska och kemiska indikatorer – Provningsutrustning (ISO 18472:2018)

Sterilization of health care products – Biological and chemical indicators – Test equipment (ISO 18472:2018)

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Europastandarden EN ISO 18472:2018 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 18472:2018.

Denna standard ersätter SS-EN ISO 18472:2006, utgåva 1

The European Standard EN ISO 18472:2018 has the status of a Swedish Standard. This document contains the official version of EN ISO 18472:2018.

This standard supersedes the SS-EN ISO 18472:2006, edition 1

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Rengöring, desinfektion och sterilisering, SIS/TK 349.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 18472

September 2018

ICS 11.080.01

Supersedes EN ISO 18472:2006

English Version

Sterilization of health care products - Biological and chemical indicators - Test equipment (ISO 18472:2018)

Stérilisation des produits de santé - Indicateurs biologiques et chimiques - Appareillage d'essai (ISO 18472:2018)

Sterilisation von Produkten für die Gesundheitsfürsorge - Biologische und chemische Indikatoren - Prüfausrüstung (ISO 18472:2018)

This European Standard was approved by CEN on 9 May 2018.

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, Serbia, 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

Ref. No. EN ISO 18472:2018: E

Contents

Page

European foreword

This document (EN ISO 18472:2018) has been prepared by Technical Committee ISO/TC 198 "Sterilization of health care products" in collaboration with Technical Committee CEN/TC 102 “Sterilizers and associated equipment for processing of medical devices” 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 March 2019, and conflicting national standards shall be withdrawn at the latest by March 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 18472:2006.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 18472:2018 has been approved by CEN as EN ISO 18472:2018 without any modification.

Introduction

To test the performance of biological and chemical indicators, specific test equipment is required. This document specifies the performance requirements for the test equipment to be used to establish the response of biological and chemical indicators to critical process variables. This document does not apply to test equipment for indicators used in irradiation, isolator/room biodecontamination (at atmospheric pressure), or low temperature steam and formaldehyde processes.

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 the appropriate parts of 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 measurement 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 measurement accuracy. Practical design takes the following into consideration:

— 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

This document specifies the requirements for test equipment to be used to:

— test biological indicators for steam, ethylene oxide gas and dry heat sterilization processes for conformity to the requirements given in ISO 11138 series;

— test chemical indicators for steam, ethylene oxide gas, dry heat and vaporized hydrogen peroxide sterilization processes for conformity to the requirements given in ISO 11140-1:2014.

This document also provides informative methods useful in characterizing the performance of biological and chemical indicators for intended use and for routine quality control testing.

This document does not specify requirements for test equipment for processes specifically for testing chemical and biological indicators intended to monitor isolator and room biodecontamination processes at atmospheric pressure.

ISO 11138-2:2017, ISO 11138-3:2017, ISO 11138-4:2017 and ISO 11140-1:2014 require the use of resistometers specified in this document, and these resistometers are used in conjunction with the test methods specified in the appropriate parts of ISO 11138 series and ISO 11140 series.

Resistometers for low temperature steam and formaldehyde indicators are not included in this document. Test methods using laboratory apparatus for low temperature steam and formaldehyde are included in ISO 11138-5:2017.

Test equipment for testing Type 2 (e.g. Bowie Dick) chemical indicators are specified in ISO 11140-3:2007, ISO 11140-4:2007, and ISO 11140-5:2007.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11138-1:2017, *Sterilization of health care products — Biological indicators — Part 1: General requirements*

ISO 11138-2:2017, *Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes*

ISO 11138-3:2017, *Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes*

ISO 11138-4:2017, *Sterilization of health care products — Biological indicators — Part 4: Biological indicators for dry heat sterilization processes*

ISO 11138-5:2017, *Sterilization of health care products — Biological indicators — Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes*

ISO 11140-1:2014, *Sterilization of health care products — Chemical indicators — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11138-1:2017, ISO 11138-2:2017, ISO 11138-3:2017, ISO 11138-4:2017, ISO 11138-5:2017, and ISO 11140-1:2014 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at https://www.iso.org/obp

3.1
biological indicator
test system containing viable microorganisms providing a specified resistance to a specified sterilization process

[SOURCE: ISO 11139:2018, 3.29]

3.2
calibration
operation that, under specified conditions, in a first step, establishes a relation between the quantity values with measurement uncertainties provided by the measurement standards and corresponding indications with associated measurement uncertainties and, in a second step, uses this information to establish a relation for obtaining a measurement result from an indication

[SOURCE: ISO/IEC Guide 99:2007, 2.39, modified — NOTE 1, 2, and 3 have been deleted.]

3.3
chemical indicator
test system that reveals change in one or more pre-specified process variables based on a chemical or physical change resulting from exposure to a process

[SOURCE: ISO 11139:2018, 3.43]

3.4
come-down period
<resistometer> time elapsed from the termination of the exposure period to an established null reaction point

[SOURCE: ISO 11139:2018, 3.56]

3.5
come-up period
<resistometer> time elapsed from the introduction of the sterilizing agent to the attainment of the specified conditions

[SOURCE: ISO 11139:2018, 3.57]

3.6
indicator exposure period
duration between the initial attainment to the termination of the specified exposure conditions

[SOURCE: ISO 11139:2018, 3.140]

3.7
measurement accuracy
closeness of the agreement between a measured quantity value and a true quantity value of a measurand

Note 1 to entry: “Accuracy” is a qualitative concept.

Note 2 to entry: The term “precision” should not be used for “accuracy”.

[SOURCE: ISO/IEC Guide 99:2007, 2.13, modified — The terms “accuracy of measurement” and “accuracy” have been deleted. NOTE 1 and 2 have been modified. NOTE 3 has been deleted.]

3.8
measurement precision
closeness of agreement between indications or measured quantity values obtained by replicate measurements on the same or similar objects under specified conditions

Note 1 to entry: Measurement precision is usually expressed numerically by measures of imprecision, such as standard deviation, variance, or coefficient of variation under the specified conditions of measurement.

Note 2 to entry: The ‘specified conditions’ can be, for example, repeatability conditions of measurement, intermediate precision conditions of measurement, or reproducibility conditions of measurement.

Note 3 to entry: Measurement precision is used to define “measurement repeatability”, “intermediate measurement precision”, and “measurement reproducibility”.

Note 4 to entry: Sometimes “measurement precision” is erroneously used to mean measurement accuracy.

[SOURCE: ISO/IEC Guide 99:2007, 2.15, modified — The term “precision” has been deleted. The NOTEs have been modified.]

3.9
null reaction point
terminating set of conditions that have no significant effect on the indicator

3.10
record, verb
<data> collect, store and make accessible

[SOURCE: ISO 11139:2018, 3.223]

3.11
reference standard
measurement standard designated for the calibration of other measurement standards for quantities of a given kind in a given organization or at a given location

[SOURCE: ISO/IEC Guide 99:2007, 5.6, modified — The term name has been simplified.]

3.12
resistometer
test equipment designed to create specified combinations of the physical and/or chemical parameters of a sterilization process

[SOURCE: ISO 11139:2018, 3.233]

3.13
response time
τ_{90}
<sensor> period required for a 90 % change in sensor output when exposed to a step change in the variable being measured

Note 1 to entry: It may be necessary to determine the sensor response time using a faster data sampling rate than the minimum for the equipment specified in this document. Documentary evidence from the sensor manufacturer's stated response time is equally acceptable as proof of conformance.

[SOURCE: ISO 11139:2018, 3.234, modified — Note 1 to entry has been added.]

3.14
saturated steam
water vapour in a state of equilibrium between its liquid and gas phases

[SOURCE: ISO 11139:2018, 3.241]