

STN	Sterilizácia výrobkov na zdravotnú starostlivosť Biologické a chemické indikátory Skúšobné metódy (ISO 18472: 2018)	STN EN ISO 18472 85 5013
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Sterilization of health care products - Biological and chemical indicators - Test equipment (ISO 18472:2018)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 03/19

Obsahuje: EN ISO 18472:2018, ISO 18472:2018

Oznámením tejto normy sa ruší
STN EN ISO 18472 (85 5013) z októbra 2006

128295

EUROPEAN STANDARD

EN ISO 18472

NORME EUROPÉENNE

EUROPÄISCHE NORM

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)

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EN ISO 18472:2018 (E)

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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of an identical text or by endorsement, at the latest by March 2019, and conflicting national standards shall be withdrawn at the latest by March 2019.

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Endorsement notice

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

INTERNATIONAL STANDARD

ISO
18472

Second edition
2018-08

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

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



Reference number
ISO 18472:2018(E)

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Published in Switzerland

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ISO 18472:2018(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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

This second edition cancels and replaces the first edition (ISO 18472:2006), which has been technically revised.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN