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GB/T 24628-2025 / ISO 18472:2018

Replacing GB/T 24628-2009

**Sterilization of Health Care Products – Biological and
Chemical Indicators – Test Equipment**

(ISO 18472:2018, IDT)

医疗保健产品灭菌 生物与化学指示物 测试设备

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Foreword

This Document was drafted as per the rules specified in GB/T 1.1-2020 *Directives for Standardization – Part 1: Rules for the Structure and Drafting of Standardizing Documents*.

This Document replaced GB/T 24628-2009 *Sterilization of Health Care Products - Biological and Chemical Indicators - Test Equipment*. Compared with GB/T 24628-2009, the major technical changes of this Document are as follows besides the structural adjustments and editorial modifications:

- a) Changed the "scope" (see Clause 1 of this Edition; Clause 1 of the 2009 Edition);
- b) Change the definition of the term "calibration" (see 3.2 of this Edition; 3.2 of the 2009 Edition);
- c) Delete "non-biological indicator" from the term "chemical indicator" (see 3.3 of the 2009 Edition);
- d) Change the term and definition of "exposure period" (see 3.6 of this Edition; 3.6 of the 2009 Edition);
- e) Change the term and definition of "precision" (see 3.8 of this Edition; 3.9 of the 2009 Edition);
- f) Change the definition of "zero-effect point" (see 3.9 of this Edition; 3.8 of the 2009 Edition);
- g) Add the terms "record (verb)" and "sterilizer" (see 3.10 and 3.17 of this Edition);
- h) Change the definition of "reference standard" (see 3.11 of this Edition; 3.10 of the 2009 Edition);
- i) Change the definition of "response time" (see 3.13 of this Edition; 3.12 of the 2009 Edition);
- j) Change the definition of "saturated steam" (see 3.14 of this Edition; 3.13 of the 2009 Edition);
- k) Change the definition of "steady-state period" (see 3.16 of this Edition; 3.15 of the 2009 Edition);
- l) Delete "measurement and control capability" (see 4.2 of the 2009 Edition);
- m) Change the test method for resistometers (see 4.2 of this Edition; 4.3 of the 2009 Edition);
- n) Change the performance requirements for steam resistometers (see 4.4 of this Edition);

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 GB/T 18281 (all parts);
- test chemical indicators for steam, ethylene oxide gas, dry heat and vaporized hydrogen peroxide sterilization processes for conformity to the requirements given in GB/T 18282.1-2025.

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.

GB/T 18281.2-2024, GB/T 18281.3-2024, GB/T 18281.4-2024 and GB/T 18282.1-2025 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 GB/T 18281 (all parts) and ISO 11140 (all parts).

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.

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 GB/T 18281.5-2024.

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 provisions in following documents become the essential provisions of this Document through reference in this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

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