

ICS 11.080.01
CCS C 47



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 18282.6-2026

**Sterilization of health care products - Chemical indicators - Part
6: Type 2 indicators and process challenge devices for use in
performance testing of small steam sterilizers**

医疗产品灭菌 化学指示物 第6部分：用于小型蒸汽灭菌器性能测试的二类指示物
和过程挑战装置

(English Translation)

Issued on: January 28, 2026

Implemented on: August 1, 2027

Issued by: State Administration for Market Regulation

Table of Contents

Preface
Introduction
1 Scope
2 Normative References
3 Terms and Definitions
4 Requirements
5 Dry heat properties of chemical indicators
6 Marking and Labeling
Appendix A (Informative) A list of structural designations in this document compared to ISO 11140-6:2022 (Table 12)
Appendix B (Informative) A summary of the technical differences between this document and ISO 11140-6:2022 and the reasons thereof (Table 13)
Appendix C (Informative) Relationships between the components of a chemical indicator
Appendix D (Informative) Accelerated Aging of Test Samples
Appendix E (Normative) Performance Test Methods for Cavity Indicator Systems (RHIS)
Appendix F (Normative) Performance Test Methods for Alternative Porous Indicator Systems (APIS)
Appendix G (Normative) Reference Cavity Devices (RHD)
Appendix H (Normative) Performance Test Methods for Alternative Cavity Indicator Systems (AHIS)
Appendix I (Informative) Evaluation of Reference Cavity Devices (RHDs) - Interlaboratory Results
References

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 6 of GB (GB/T) 18282. GB/T 18282 has the following parts published.

---GB/T 18282.1-2025 Chemical Indicators for Sterilization of Medical and Health Products Part 1: General Rules;

---GB 18282.3-2009 Chemical Indicators for Sterilization of Medical and Health Products -

Part 3: For Class BD Vapor Permeation Testing Class II indicator systems;

---GB 18282.4-2009 Chemical Indicators for Sterilization of Medical and Health Products

Part 4: For Use with Alternative BD Class Steam Infiltration Type II indicators for penetration testing;

---GB 18282.5-2015 Chemical Indicators for Sterilization of Medical and Health Products -

Part 5: For Class BD Air Exclusion Testing Class II indicators;

The test includes two types of indicators and process challenge devices.

This document is modified to adopt ISO 11140-6:2022 "Chemical indicators for sterilization of healthcare products - Part 6: Use in small steam sterilizers".

Two types of indicators and process challenge devices for testing the performance of sterilization equipment.

Compared with ISO 11140-6:2022, this document has undergone many structural adjustments. A comparison of the structural numbering changes between the two documents is provided below.

See Appendix A for the table.

This document differs significantly from ISO 11140-6:2022. The relevant clauses are indicated in the margins using vertical markers.

Straight lines (|) are marked. A summary of these technical differences and their reasons can be found in Appendix B.

The following editorial changes have been made to this document.

---The warning section before the range has been removed;

---The vacuum depth in cycle 3 of section 4.3.4.1 of ISO 11140-6:2022 has been modified;

---Added a note referring to Appendix I (see 4.6.1);

---The clause "This symbol should not be translated or used" in section 6.1.1 of ISO 11140-6:2022 has been removed;

---The clause "This symbol should not be translated or used" in section 6.1.2 of ISO 11140-6:2022 has been removed;

---The clause "This symbol should not be translated or used" in section 6.1.3 of ISO 11140-6:2022 has been removed;

---The saturated vapor content of non-condensable gases in 100 mL of vapor condensate in Annex A of ISO 11140-6:2022 has been modified;

---The background information regarding EN867-5 and EN285:2006 A2.2009 in Annex G of ISO 11140-6:2022 has been removed.

The description section of ISO TS17665-2:2009;

---The window size parameter and maximum pressure for failure conditions in Annex G of ISO 11140-6:2022 have been modified;

---The window size parameter in Annex G.4.3 of ISO 11140-6:2022 has been changed;

---The minimum pressure obtained under successful conditions in Annex G.4.4 of ISO 11140-6:2022 has been modified;

---The maximum pressure displayed for failure conditions in Annex G.4.5 of ISO 11140-6:2022 has been changed;

---The window size parameter in G.4.6 of Annex G in ISO 11140-6:2022 has been changed;

--- EN13060:2014 A1.2018 has been replaced with YY/T 0646-2022, which is used for informational reference.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Disinfection Technology and Equipment (SAC/TC200).

Introduction

GB (GB/T) 18282 "Chemical Indicators for Sterilization of Medical Products" is the fundamental and universal standard for chemical indicators in my country.

Standard. GB (GB/T) 18282 aims to establish the performance requirements and/or test methods for indicators and indicator systems, and is proposed to consist of five parts.

---Part 1: General Rules. The purpose is to establish the performance requirements and/or testing methods for chemical indicators.

---Part 3: Class II Indicator Systems for Class BD Vapor Permeability Testing. The aim is to establish a system for class BD vapor permeability testing...

The performance of the two-category indicator system tested was evaluated for sterilizers used for sterilizing packaged and porous loads.

---Part 4: Class II Indicators for Alternative BD Class Vapor Permeability Testing. The aim is to establish alternative indicators for BD class vapor permeability testing.

The Class II indicator system for vapor permeation testing is used to perform performance tests on sterilizers used for both packaged and porous load sterilization.

---Part 5: Class II Indicators for Class BD Air Purging Tests. The purpose is to establish indicators for use in Class BD air purging tests.

Class II indicators are used to evaluate the air removal effectiveness of the pre-vacuum stage in a pre-vacuum sterilization cycle.

---Part 6: Class II Indicators and Process Challenge Devices for Performance Testing of Small-Scale Steam Sterilizers. The aim is to clarify the performance characteristics of small-scale steam sterilizers.

The process of testing sterilizer performance involves challenging equipment and associated chemical indicators.

This document describes the performance requirements for cavity and porous process challenge devices (PCDs), and demonstrates alternative process challenge devices compared to reference ones.

The process challenges the device to have the same performance. A sterilization unit [300mm (height) x] cannot be accommodated for the following reasons.

A small sterilizer with a cuboid shape measuring 600mm (length) x 300mm (width) cannot be sterilized using the methods described in GB 8599-2023.

Line test.

---The chamber size of a small steam sterilizer conforming to YY/T 0646 cannot accommodate the standard test conforming to GB 8599-2023.

Bag, and

---The validity of the test is affected when the test pack occupies a large proportion of the chamber volume (more than 20% of the chamber volume).

(Accumulated time).

The indicators described in this document are intended for use with a suitable process challenge device to indicate steam permeation into the process challenge device.

Reference indicator systems and alternative indicator systems present specific challenges to air removal and vapor permeation.

The apparatus described in this document is only applicable to small steam sterilizers conforming to YY/T 0646, used for monitoring Type B cycles and certain...

S-shaped cycle vapor permeation performance.

Note: Although the cavity load test was originally designed for type testing to evaluate the performance of small steam sterilizers conforming to YY/T 0646, this test is also applicable to...

For use in other standards, such as GB 8599-2023.