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

GB 18282.4-2009

**Sterilization of health care products - Chemical indicators - Part
4: Class 2 indicators as an alternative to the Bowie and
Dick-type test for detection of steam penetration**

医疗保健产品灭菌 化学指示物 第4部分：用于替代性BD类蒸汽渗透测试的二类指示物

(English Translation)

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Foreword

All the technical contents in this Part are mandatory.

GB 18282 Sterilization of Health Care Products - Chemical Indicators consists of the following

parts.

--- Part 1.General;

--- Part 3.Class 2 Indicator Systems for Use in the Bowie and Dick-Type Steam Penetration Test;

--- Part 4.Class 2 Indicators as an Alternative to the Bowie and Dick-Type Test for Detection of Steam Penetration;

--- Part 5.Class 2 Indicators for Bowie and Dick-Type Air Removal Tests.

This Part is Part 4 of GB 18282.

This Part equivalently adopts ISO 11140-4.2007 Sterilization of Health Care Products - Chemical Indicators - Part 3.Class 2 Indicators as an Alternative to the Bowie and Dick-Type

Test for Detection of Steam Penetration.

Compared with ISO 11140-4.2007, the major differences with this Part are as follows.

- Make the editorial modifications as per the requirements in GB/T 1.1;
- Delete the Foreword of the international standard;
- For other international standards cited in this Part, if they have been converted into Chinese standards, this Part will replace the referenced international standard number with the corresponding national standard number, and indicate the adoption relationship.

The Annexes A ~ L of this Part are normative.

This Part was proposed by China Food and Drug Administration.

This Part shall be under the jurisdiction of National Technical Committee on Disinfection Technology and Equipment of Standardization Administration of China (SAC/TC 200).

Drafting organizations of this Part. Guangzhou Medical Device Quality Supervision and Inspection Center of State Food and Drug Administration; and Shinva Medical Instrument Co.,

Ltd.; and 3M China Ltd.

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1 Scope

This Part of GB 18282 specifies the performance for a Class 2 indicator to be used as an alternative to the Bowie and Dick-type test for steam sterilizers for wrapped health care goods

(instruments, etc., and porous loads).

2 Normative References

The provisions in following documents become the provisions of this Part through reference in

this Part of GB 18282. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document

applies.

GB/T 11501 Photography - Density Measurement - Part 3.Spectral Conditions (GB/T 11501-2008, ISO 5-3.1995, IDT)

3 Terms and Definitions

For the purposes of this Part of GB 18282, the terms and definitions given in ISO 11140-1 and

the following apply.

Indicator in which the user combines the indicator system with the test load prior to use.

4 General Requirements

Compliance with the requirements of this Part of GB 18282 shall be determined by establishing conformity with the performance requirements of Clause 6.

5 Indicator System Format

When the indicator system is provided by the manufacturer already incorporated into the test load, the material of either the indicator or the indicator system, as appropriate, shall permit

writing to be made after processing.

6 Performance Requirements

Indicators intended for use only with specific air removal cycles shall be tested with those specific cycles only (see 5.7 of ISO 11140-1.2005).

7 Packaging and Labelling

When a manufacturer provides similar products which are intended only for specific sterilization cycles, the product shall include identification sufficient to enable the user to determine, from the instructions for use, any restrictions on the use of the product.

8 Quality Assurance

The quality system shall ensure that the performance requirements given in Clause 6 are maintained.

Suitable records shall be maintained to ensure that, if necessary, faulty batches can be recalled from use.

Annex A

(Normative)

Determination of Indicator Strength during and after Steam Sterilization

Steam exposure apparatus, as specified in Annex J.

Annex B

(Normative)

Standard Test Cycles

The standard test cycle for sub-atmospheric air removal shall consist of the following steps.

Annex C

(Normative)

Estimation of Visual Difference Between Color of the Substrate and of the

Changed or Unchanged Indicator System by Determination of Relative

Reflectance Density

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