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

GB 18282.3-2009

**Sterilization of health care products - Chemical indicators - Part
3: Class 2 indicator systems for use in the Bowie and Dick-type
steam penetration test**

医疗保健产品灭菌 化学指示物 第3部分：用于BD类蒸汽渗透测试的二类指示物系统

(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 3 of GB 18282.

This Part equivalently adopts ISO 11140-3:2007 Sterilization of Health Care Products - Chemical Indicators - Part 3: Class 2 Indicator Systems for Use in the Bowie and Dick-Type Steam Penetration Test.

Compared with ISO 11140-3:2007, 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 ~ K of this Part are normative.

This Part was proposed by State 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; Beijing Medicare Jincheng Medical

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Sterilization of Health Care Products - Chemical Indicators

- Part 3: Class 2 Indicator Systems for Use in the Bowie and

Dick-Type Steam Penetration Test

1 Scope

This Part of GB 18282 specifies the requirements for chemical indicators to be used in the steam penetration test for steam sterilizers for wrapped goods, e.g., instruments and porous

materials. The indicator for this purpose is a Class 2 indicator as described in ISO 11140-1.

Indicators complying with this Part of GB 18282 are intended for use in combination with the

standard test pack as described in EN 285. This Part of GB 18282 does not consider the performance of the standard test pack, but does specify the performance of the indicator systems.

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)

GB/T 12823.1 Photography - Density Measurement - Part 1: Terms, Symbols and Notations (GB/T 12823.1-2008, ISO 5-1:1984, IDT)

GB/T 12823.4-2008 Photography - Density Measurement - Part 4: Geometric Conditions for Reflection Density (ISO 5-4:1995, IDT)

ISO 187:1990 Paper, Board and Pulps -- Standard Atmosphere for Conditioning and Testing and Procedure for Monitoring the Atmosphere and Conditioning of Samples

ISO 2248 Packaging - Complete, Filled Transport Packages - Vertical Impact Test by Dropping manufacturer.

Compliance shall be tested in accordance with Annex B.

f) It shall permit writing in permanent ink to be made legibly on both processed and unprocessed materials. Markings made before processing shall be legible after processing.

g) It shall be of size A4 in accordance with ISO 5457.

6.1 The indicator shall meet the following requirements.

a) It shall show a uniform color change complying with 5 e) after exposure to dry saturated steam at 134 (+1.5 0) °C for 3.5 min ± 5 s or after exposure to dry saturated steam at 121

(+1.5 0)°C for 15 min ± 5 s or both.

Compliance shall be tested in accordance with Annex C.

b) When placed in the center of a standard test pack, it shall show a non-uniform color change when the temperature at the center of the standard test pack is 2°C lower than the temperature of the chamber drain of the steam exposure apparatus (see Annex H).

Compliance shall be tested in accordance with Annex I.

c) It shall show no discernible color change after exposure to dry heat at $(140 \pm 2)^{\circ}\text{C}$ for not less than 30 min.

Compliance shall be demonstrated in accordance with Annex D.

With some indicators a slight color change can occur. This shall be acceptable if the change that occurs is markedly different from that brought about by exposure to steam in accordance with 6.1 a) and within the limits specified by the manufacturer.

d) It shall not visibly transfer indicator reagent to the material of the test load in intimate contact with the indicator during processing.

Compliance shall be demonstrated in accordance with Annex F.

6.2 The indicator shall comply with the requirements of this part of GB 18282 for the duration

of the shelf life specified by the manufacturer.

If any change in the indicator occurs during ageing, it shall be different to the change on exposure to dry saturated steam [as described in 6.1 a)], and shall have either inactivated the

indicator so that no further change can take place or not affected the performance of the

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