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

GB 18282.5-2015

**Sterilization of health care products-Chemical indicators-Part 5:
Class 2 indicators for Bowie and Dick-type air removal tests**

医疗保健产品灭菌 化学指示物 第5部分：用于BD类空气排除测试的二类指示物

(English Translation)

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Foreword

All technical contents of this Part of GB 18282 are mandatory.

GB 18282 Sterilization of health care products - Chemical indicators is divided into the following parts:

- Part 1: General requirements;
- 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.

Note: GB 18282.2 Sterilization of health care products - Chemical indicators - Test equipment and methods is replaced by GB/T 24628-2009 Sterilization of health care products - Biological and chemical indicators - Test equipment.

This Part is Part 5 of GB 18282.

This Part was drafted in accordance with the rules given in GB/T 1.1-2009.

This Part is identical to ISO 11140-5:2007 Sterilization of health care products -

Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal tests.

The documents of China, which have a consistent correspondence with the international documents referenced in this Part, are as follows:

- GB/T 12823.4-2008 Photography - Density measurement - Part 4: Geometric conditions for reflection density (ISO 5-4:1995, IDT);
- GB/T 16839.2-1997 Thermocouples - Part 2: Tolerances (IEC 60584-2:1982+A1:1989, IDT);
- GB 18282.1-2015 Sterilization of health care products - Chemical indicator - Part 1: General requirements (ISO 11140-1:2005, IDT).

This Part makes the following editorial changes:

- Make some editorial modifications in accordance with the requirements of GB/T 1.1;
 - Delete Foreword of the international standard;
- Sterilization of health care products - Chemical indicators -
Part 5: Class 2 indicators for Bowie and Dick-type air
removal tests

1 Scope

This Part of GB 18282 specifies the requirements for Class 2 indicators for Bowie and Dick-type air removal tests used to evaluate the effectiveness of air removal during the pre-vacuum phase of pre-vacuum steam sterilization cycles.

Additionally, this Part includes test methods and equipment used to meet these performance requirements.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies to this document. For undated references, the latest edition (including any amendment) applies to this document.

ISO 5-4:1995, Photography - Density measurements - Part 4: Geometric conditions for reflection density

ISO 5636-3, Paper and board - Determination of air permeance (medium range) - Part 3: Bendtsen method

ISO 11140-1:2005, Sterilization of health care products - Chemical indicators - Part 1: General requirements

IEC 60584-2:1982, Thermocouples - Part 2: Tolerances

IEC 60751:1983, Industrial platinum resistance thermometer sensors

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11140-1 and the following apply.

5.1.4 The indicator system shall have an air porosity not less than $1.7 \mu\text{m}/(\text{Pa}\cdot\text{s})$ when

tested in accordance with ISO 5636-3 at an air pressure of 1.47 kPa.

5.2.1 The indicator system shall show a uniform colour change (as specified by the

manufacturer) after exposure to saturated steam at 134°C for $3.5 \text{ min} \pm 5 \text{ s}$ and/or exposure to saturated steam at 121°C for $15 \text{ min} \pm 5 \text{ s}$, or such other combinations of time and temperature as the manufacturer shall specify for the intended use of product.

In all cases, the permitted tolerance on the test temperature shall be $+1.5^{\circ}\text{C}$ and the time given shall be the time within which the colour change shall occur.

Compliance shall be tested in accordance with Appendix B.

5.2.2 When placed in the centre of the standard test pack as specified in Appendix E,

the indicator system shall show a non-uniform colour change when the temperature at the centre of the standard test pack is $2 \pm 1^{\circ}\text{C}$ lower than the temperature of the chamber drain at the beginning of the final 1 min of a 3.5 min cycle at 134°C , or at the beginning of the final 5 min of a 15 min cycle at 121°C of the exposure phase of the steam

exposure apparatus. This is the standard fault condition generated by inadequate air removal from the chamber. Any other combination of time and temperature stated by the manufacturer shall exhibit a similar response at the beginning of the final 30% of the exposure time.

Compliance shall be tested in accordance with Appendix F.

5.2.3 After exposure to dry heat at $(140 \pm 2)^{\circ}\text{C}$ for not less than 30 min, the indicator

agent shall show either no change or a change that is markedly different from the change occurring after exposure to a steam sterilization process.

Compliance shall be tested in accordance with Appendix C.

5.2.4 Transfer of the indicator agent to the material of the standard test pack in which it

is intended to be used shall not compromise the result of the test.

Compliance shall be tested in accordance with Appendix D.

Note: Although some transfer can be possible without adversely affecting the performance of the indicator system or test pack, there are currently no test methods available to verify the acceptable limits of indicator agent transfer.

5.2.5 The indicator system shall comply with the requirements of this Part for the duration of the shelf life specified by the manufacturer.

A documented accelerated ageing procedure may be used in demonstrating compliance.

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