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

GB 18281.5-2015

**Sterilization of health care products -- Biological indicator --
Part 5: Biological indicators for low-temperature steam and
formaldehyde sterilization processes**

医疗保健产品灭菌 生物指示物

(English Translation)

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Table of Contents

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 1 General requirements

5 test bacteria

6 1 bacterial suspension

7 carrier and the inner packaging

8 carrier contamination and biological indicators

9 Number of microbial resistance and

Annex B (informative) low temperature steam formaldehyde principle with liquid
biological indicators Test Method

1 Scope

GB 18281 of the provisions of this part of the test microorganisms, bacterial suspension, the carrier contamination, biological indicator and low temperature steam formaldehyde sterilization

General requirements for sterilization agent to assess the treatment effect of biological indicator test method.

Note 1: The requirements for low temperature steam formaldehyde sterilization process control and confirmation, see ISO 14937.

Note 2: For the safety requirements in the workplace, see national or regional regulations.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein

Member. For undated references, the latest edition (including any amendments) applies to this document.

ISO 11138-1:2006 Sterilization of health care products - Biological indicators - Part

1.General (Sterilization of health care products-Biological indicators-Part

1.General requirements)

3 Terms and Definitions

As defined in ISO 11138-1 and the following terms and definitions apply to this document.

3.1 Low temperature steam formaldehyde sterilization

By the power exhaust, so that pre-packaged goods in the vacuum state is exposed to steam at temperatures below 100 °C, the injection of formaldehyde gas,

Such sterilizing agents in the maintenance time remains steady process.

4 General requirements

ISO 11138-1 requirements apply to this section.

5.1

Test bacteria should be *Bacillus stearothermophilus* or other has been found to comply with the requirements of this strain of microorganism equivalent performance.

Note 1: *Bacillus stearothermophilus* have been reclassified to *Bacillus stearothermophilus*.

Note 2: The currently considered applicable to *Bacillus stearothermophilus*, as NCIB8224, DSM6790, ATCC10149 and ATCC12980.

5.2

If the use of a test bacteria *Bacillus stearothermophilus* ground outside, then this strain of bacteria resistance test suitability should be determined.

6 bacterial suspension

ISO 11138-1 requirements apply to this section.

7.1

low temperature steam formaldehyde sterilization agent biological indicator carriers and inner packing material should conform to ISO 11138-1.2006 5.2

And ISO 11138-1.2006 requirements in Appendix B of.

Note: Due to the cellulose surface chemical formaldehyde adsorption filter paper type is not suitable as a carrier.

7.2

should comply with the determined exposure conditions.

- a) Minimum temperature exposure. not less than 5 °C (above the manufacturer claims the highest temperature);
- b) maximum exposure temperature. According to the manufacturer's maximum claims; If the manufacturer is not declared, should not be less than the maximum exposure temperature 100 °C;
- c) Exposure time. not less than 60min.

Note: These conditions have become a caution, with practical limits on bacteria in the range of application of low temperature steam formaldehyde sterilization process. Selection criteria to be able to significantly

It shows the actual low temperature steam formaldehyde sterilization process to the actual requirements of the carrier.

8 carrier contamination and biological indicators

ISO 11138-1 requirements apply to this section.

9.1

Manufacturers should be based on ISO 11138-1:2006 6.4 Characteristics of predetermined resistance requirements.

9.2

Proliferation amount viable count should be less than 0.1×10^n /per unit (eg. bacteria per ml suspension, each to be inoculated with bacteria, each student

Adhesive tape cells).

With cell proliferation and the amount of biological cells with 9.3 to be vaccinated should be not less than 1.0×10^5 .

9.4

resistance should be expressed as D value at 60 °C, and in minutes (min). Each batch/lot of contamination or biological indicator carriers D

D values apply at 60 °C that is kept to one decimal place.

9.5

when tested in accordance with Appendix A, the medium carrier contamination or biological indicator comprises D60 value to steartothermophilus Bacillus

Should ≥ 6 min. Other micro-organisms should also be applied to the D value.

Resistance 9.6 biological indicator can also be used FBIO value indicates (see ISO 11138-1:2006 3.7). This section GB 18281 and its

The specific part of his resistance shall be tested in accordance with specific conditions standards.

9.7

shall be according to ISO 11138-1:2006 Determination of D value of Appendices C and D of the given method.

9.8

D value determination and survival - kill response characteristics based on the process parameters in Appendix A.

9.9

Survival - killing range available ISO 11138-1:2006 Appendix E formula to calculate.

NOTE: To compare different batches of the same manufacturer's product information for the user is useful.

Example. Apply ISO 11138-1:2006 Appendix E of the formula and the population and minimum D values given in this section, survival - kill reaction characteristic values are.

--- 60 °C when. survival time ≥ 18 min, kill time ≤ 54 min.

Appendix A (Normative)

Determination of low temperature steam formaldehyde sterilization process resistance method

A.1 General

This method is based on a carrier immersed in formalin contamination qualitative testing. The results of this test method than the use of gas cavity

The results of the method have better reproducibility.

A.3 provides the special requirements of the test method.