ICS 11.080.01
CCS C 47

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 19972-2018

Sterilization of health care products -- Biological indicators -- Guidance for the selection, use and interpretation of results

Issued on: March 15, 2018 **Implemented on: October 1, 2018**

Issued by: State Administration for Market Regulation, China National Standardization Administration

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Foreword

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

This standard replaces GB/T 19972-2005 "Guidelines for the Selection, Use and Result Judgment of Sterilized Biological Indicators for Healthcare Products".

The main technical differences between this standard and GB/T 19972-2005 are as follows.

--- Added "duration", "installation identification", "running identification", "performance identification", "process variable", "reference microorganism", "spore log reduction"

Terms and definitions of "less value" "sterility assurance level" and "survival-kill interval" (see 3.6, 3.8, 3.11, 3.12, 3.16, 3.17, 3.19,

3.21 and 3.26);

--- Added the informative appendix "calculation of z values" (see Appendix E);

--- Added the informative appendix "survival curve method to measure D value" (see Appendix F);

--- Added the informative appendix "Survival-killing response characteristics (see Appendix G)".

This standard uses the translation method equivalent to the ISO 14161.2009 "healthcare product sterilization biological indicator selection, use and knot

Judgment Guide.

The documents of our country that have a consistent correspondence with the international

documents referenced in this standard are as follows.

---GB 18278.1-2015 Health care products Sterilization and moist heat Part 1. Development, validation and validation of medical device sterilization processes

General control requirements (ISO 17665-1.2006, IDT)

---GB 18279.1-2015 Health care products Sterilization of ethylene oxide Part 1. Development of medical device sterilization process, indeed

Recognition and routine control requirements (ISO 11135-1.2007, IDT)

--- GB 18281.1-2015 Sterilization of biological indicators for health care products - Part 1. General (ISO 11138-1.2006,

IDT)

--- GB 18281.2-2015 Sterilization of biological indicators for health care products - Part 2. Biological indications for the sterilization of ethylene oxide

(ISO 11138-2.2006, IDT)

--- GB 18281.3-2015 Sterilization of biological indicators for health care products - Part 3. Biological indicators for moist heat sterilization

(ISO 11138-3.2006, IDT)

--- GB 18281.4-2015 Sterilization of biological indicators for health care products - Part 4. Biological indicators for dry heat sterilization

(ISO 11138-4.2006, IDT)

--- GB 18281.5-2015 Sterilization of biological indicators for health care products - Part 5.

Indicator (ISO 11138-5.2006, IDT)

--- GB/T 19973.1-2015 Microwaveological methods for the sterilization of medical devices - Part 1

Ding (ISO 11737-1.2006, IDT)

---GB/T 19974-2005 Characteristics of Sterilization Factor of Healthcare Products and Setting and Confirmation of Sterilization Process of Medical Devices

General requirements for general control and control (ISO 14937.2000, IDT)

Introduction

This standard provides guidance on the selection, use, and determination of biological indicators when applied to the development, validation, and monitoring of sterilization processes.

The procedures described in this standard are of a general nature and are not themselves a comprehensive development, validation and monitoring process for the sterilization of healthcare products.

sequence. The purpose of this standard is not to force the use of biological indicators in a process, but to correctly select them if biological indicators are used.

Choose and use guidelines to avoid misleading results.

In this standard, users can obtain biological indicator selection guides for specific sterilization processes and key parameters, and use the health correctly.

A guide to objects.

The user should select a biological indicator that is appropriate for the particular sterilization process they employ. Biological indications due to large differences in sterilization processes

It is difficult for the manufacturer to anticipate all possible uses of the product, so the manufacturer can only identify its biological indicator for a particular use. For mining

The specific sterilization process used should be properly selected, used, recycled, and judged by the user.

Conditions for storage and transport of biological indicators prior to use, use of biological indicators or sterilizer process parameters may be indicative of biological indicators

Adverse effects, in addition to the culture techniques used after exposure to the process, including culture temperature, media type, manufacturer and specific batches may also

It is the measured resistance associated with recovery and growth. Therefore, it should be stored and used in accordance with the recommendations of the biomarker manufacturer. After sterilization,

Biological indicators should be aseptically transferred (if applicable) and cultured as specified by the biomarker manufacturer.

It should be noted that the biological indicator is not intended to indicate that the sterilized item is indeed sterile. But to test a known sterilization process and

The effectiveness of the sterilization equipment used, which is based on the principle of assessing microbial lethality at a sterility assurance level. This

Class studies should be conducted by trained and appropriate personnel.

Health care product sterilization biological indicator

Choice, use, and results judgment guide

1 Scope

This standard provides for the selection, use, and judgment of biological indicators when applied to the development, validation, and routine monitoring of sterilization processes.

guide. This standard applies to biological indicators of existing national standards.

Note 1. See ISO 11138 for an example.

Note 2. The general information provided in this standard also applies to processes and biological indicators not mentioned in the current national standards. Such as new and developing sterilization

process.

This standard does not consider processes that physically remove microorganisms only, such as filtration.

This standard does not apply to the use of various combination processes, such as washing and sterilizing or pipe flushing and steaming.

This standard does not apply to liquid sterilization processes.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article.

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

GB/T 24628-2009 Sterilization biological and chemical indicator test equipment for healthcare products (ISO 18472.2006, IDT)

ISO 11135-1 Sterilization of ethylene oxide for health care products - Part 1. Development, validation and routine

Control requirements (Sterilizationofhealthcareproducts-Ethyleneoxide-Part 1. Requirements fordevelop-

Ment,validationandroutinecontrolofasterilizationprocessformedicaldevices)

ISO 11138-1.2006 Medicinal products - Sterilization of biological indicators - Part 1

products-Biologicalindicators-Part 1.Generalrequirements)

ISO 11138-2 Sterilization of biological indicators for health care products - Part 2. Biological indicators for the sterilization of ethylene oxide (Sterili-

zationofhealthcareproducts-Biologicalindicators-Part 2.Biologicalindicatorsforethyleneoxide