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

GB/Z 44877-2024

**Sterilization of medical devices - Guidance on using parametric
release for ethylene oxide sterilization process**
(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1. Structure and drafting rules for standardization documents"

Drafting.

This document is modified to adopt ISO /T S21387.2020 "Medical device sterilization ethylene oxide sterilization using parameter release confirmation and routine treatment

Guide to Management Requirements.

Compared with ISO /T S21387.2020, this document has made the following structural adjustments.

--- Added 6.2.1 to 6.2.5;

--- Added 9.3.3.

The technical differences between this document and ISO /T S21387.2020 and their reasons are as follows.

--- Replaced ISO 11135.2014 with the normative reference GB 18279-2023. The consistency between the two documents is

Modify it to adapt to my country's technical conditions and improve operability;

--- Added technical guidance on air flow circulation status (see 6.2) to reduce the misoperation of parameter release and reduce the application of parameter release possible risks;

--- Added guidance on determining the inactivation rate of the sterilization process according to the method given in Appendix A of GB 18279-2023 (see 8.5) to facilitate application;

--- Added technical guidance on regular online calibration of key variables (see 9.3.3) to reduce the possibility of errors after the parameters are released for a long time.

Risk of bias;

--- Added guidance on requalification (see 12.3.1) to reduce the risk of deviations that may occur after the parameters have been released for a longer period of time.

The following editorial changes have been made to this document.

--- Change the name of the document to "Guidelines for Release of Parameters of Ethylene Oxide Sterilization Process for Medical Devices";

--- Added the treatment methods when the provisions are consistent or inconsistent with GB 18279-2023 in the notes (see Chapter 1);

--- Deleted the introductory content of ISO and IEC terminology databases (see Chapter 3);

--- Replaced ISO 11135 with the informative reference GB 18279-2023 (see Chapter 1, 9.4.1.2);

--- Replaced ISO 10012 with the informative reference GB/T 19022 (see 6.3.2);

--- Added the equilibrium relative humidity relationship table of saturated salt solution at different temperatures (see Table 1);

--- Added Note 4 to 6.3.2 to remind users to prevent condensation from affecting the humidity sensor;

--- Replaced ISO 10993-7 with the informative reference GB/T 16886.7 (see 8.1);

--- Added a note to 8.5 to prompt users to select the sample size for testing D value;

--- Added two notes in 9.2.1.1 to remind users to pay attention to the number of times the ethylene oxide concentration in the sterilizer is measured and analyzed, and

Method used for concentration analysis;

--- Added Note 2 in 9.3.1 to remind users of precautions when calibrating the concentration sensor;

--- Added recommendations for statistical batch numbers (A.2.2);

--- Added the note in A.2.2 to provide an example of user calculation of sample size.

Introduction

GB 18279-2023 specifies the requirements for the development, validation and routine control of ethylene oxide sterilization processes. This document is a supplement to GB 18279-

Guiding technical documents for 2023.

GB 18279-2023, 11.1, stipulates that the criteria for qualified sterilization process of specific sterilization loads include.

- a) Ensure that the process record data of routine processing complies with the requirements of the sterilization process specification;
- b) Confirm that there is no microbial growth in all biological indicator tests (if used).

Parametric release is a statement of conformity for a confirmed routine sterilization process based solely on the monitoring results of physical process parameters.

The record is not based on the results of biological indicators, so item b) is no longer applicable.

The term "biological indicator release" is used in the declaration of conformity for a validated sterilization process and requires the inclusion of a biological indicator that has been exposed to that cycle.

No microbial growth was found in the bioassay.

This document provides examples of appropriate methods that meet the requirements of GB 18279-2023.

NOTE: Sterilization in healthcare settings differs from industrial sterilization, for example, design of processing areas, control of product bioburden, and access to information related to ethylene oxide sterilization.

Expertise and sterilization equipment that may not be equipped for parametric release.

This document is intended for personnel who are proficient in the principles of ethylene oxide sterilization and have good training. In addition to the methods given in this document, other methods

These methods may also be used if they can effectively meet the requirements of GB 18279-2023.

Medical device sterilization

Guidance on Parametric Release of Ethylene Oxide Sterilization Processes

1 Scope

This document provides guidance on the use of parametric release for sterilization release of products following an ethylene oxide sterilization process to comply with

Requirements of GB 18279-2023.

This document is applicable to providing a method for adopting parametric release for existing sterilization processes and is also applicable to developing and implementing parametric release for new sterilization processes.

This document emphasizes the importance and interrelationship of other process factors that affect the reproducibility of ethylene oxide sterilization processes, such as

Loading methods and equipment performance.

Note: For ease of use, the clause numbers in this document correspond to the clause numbers in GB 18279-2023. Clauses that are consistent with GB 18279-2023 are numbered with

"No additional guidance is given" describes inconsistent clauses and adds or modifies the corresponding content.

This document is not applicable to the release of biological indicators. For a statement of conformity for a validated sterilization cycle that includes the absence of microbial growth in a biological indicator

This document does not provide additional guidance.

2 Normative references

The contents of the following documents constitute the essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to

This document.

GB 18279-2023 Sterilization of healthcare products - Development, validation and routine control of ethylene oxide sterilization processes for medical devices

Request (ISO 11135:2014, MOD)

3 Terms and Definitions

The terms and definitions defined in GB 18279-2023 and the following apply to this document.