

ICS 11.080.01
CCS C 47



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

GB/T 18279.2-2015

**Sterilization of health care products -- Part 2: Guidance on the
application of GB 18279.1**

医疗保健产品的灭菌环氧乙烷 第2部分：GB 18279.1应用指南
(English Translation)

Issued on: December 10, 2015

Implemented on: July 1, 2017

**Issued by: General Administration of Quality Supervision, Inspection and
Quarantine of the People's Republic of China**

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Foreword

GB 18279 "Sterilization of health care products" consists of the following parts.

- Part 1. Requirements for development, validation and routine control of a sterilization process for medical devices;
- Part 2. Guidance on the application of GB 18279.1.

This Part is Part 2 of GB 18279.

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

This Part together with GB 18279.1 replaces GB 18279-2000 "Medical devices.

Validation and routine control of ethylene oxide sterilization".

This Part identically uses ISO/TS 11135-2:2008 "Sterilization of health care products - Part 2. Guidance on the application of ISO 11135-1".

The Chinese documents which have consistency with the international normative reference in this Part are as follows.

- GB 18282.1-2015, Sterilization of health care products - Chemical indicator - Part

1 General requirements (ISO 11140-1.2005, IDT);

- GB/T 19973.1-2015, Sterilization of medical devices - Microbiological methods - Part 1. Determination of a population of microorganisms on products (ISO 11737-1.2006, IDT);

- YY/T 0287-2003, Medical devices. Quality management systems. Requirements for regulatory purposes (ISO 13485.2003, IDT);

- YY/T 0802-2010, Sterilization of medical devices. Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664.2004, IDT).

This Part made the following editorial changes.

- Some editorial modifications have been made in accordance with the requirements of GB/T 1.1;

- The foreword of ISO/TS 11135-2.2008 is deleted;

- Some international standards appearing in the introduction and references are replaced by corresponding Chinese standards.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing authority shall not be held responsible for identifying any or all such patent rights.

This Part was proposed by China 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).

The drafting organizations of this Part. Hangzhou Unique Disinfection Equipment Co., Ltd., Guangzhou Medical Device Quality Supervision and Inspection Center of the State Food and Drug Administration, Terumo Medical Products (Hangzhou) Co., Ltd., Guangzhou Yangpu Medical Technology Co., Ltd., Shijie Medical Technology (Shanghai) Co., Ltd.

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Version of standard substituted by this Part is.

- GB 18279-2000.

1 Scope

This Part of GB 18279 provides guidance for the requirements in GB 18279.1-2015. It does not repeat the requirements and is not intended to be used in isolation.

The exclusions in GB 18279.1 apply also to this Part.

2 Normative references

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

person with knowledge of the sterilization technology being utilized and its effects upon materials and microorganisms

4 Quality management systems

It is recommended that the identity of the person who assembled the pack also be included on the identifier, to allow for further investigation if a problem should arise.

Lot identification information enables personnel to retrieve items in the event of a recall and to trace problems to their source.

5 Sterilizing agent characterization

EO is a highly penetrative gas that will permeate most packaging materials and polymeric materials. Widely recognized compositions include 100% EO and blends with carbon dioxide or nitrogen. The storage conditions for EO should be in accordance with the EO manufacturer's recommendations and all applicable regulations.

6 Process and equipment characterization

In health care facilities, process and equipment characterization are generally the responsibility of the sterilizer manufacturer.

The equipment specification should be reviewed to ensure that regulatory and safety requirements are met, technical specifications are appropriate, and services and infrastructure necessary to operate the equipment are available.

7 Product definition

The demonstration that the specified sterilization process does not affect the correct functioning of the product may be accomplished by performing functionality tests, or other appropriate tests, on the medical device and packaging following sterilization. These tests may range from a simple visual inspection to a battery of specialized tests.

8 Process definition

If the medical device or packaging manufacturer supplies instructions for reprocessing that are not specific enough or not appropriate (e.g., an EO process with 100 % EO, where the health care facility uses a blend), the facility should either perform a validation or assess the appropriateness of its own reprocessing method, based on materials effect data and reprocessing instructions for other devices.

9 Validation

PQ consists of rigorous microbiological and physical testing, beyond routine monitoring, to demonstrate the efficacy and reproducibility of the sterilization process. PQ is normally not started until after completion and approval of the IQ and OQ testing. Acceptance criteria should include conformance with the specifications for the sterilization process parameters and microbiological challenge.

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