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

GB 18279.1-2015

**Sterilization of health care products-Ethylene oxide-Part 1:
Requirements for development, validation and routine control of
a sterilization process for medical devices**

医疗保健产品灭菌 环氧乙烷 第1部分：医疗器械灭菌过程的开发、确认和常规控制的要求

(English Translation)

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Foreword

This document was drafted in accordance with the rules given in GB/T 1.1-2020

"Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents".

This document replaces GB 18279.1-2015 "Sterilization of health care products - Ethylene oxide - Part 1.Requirements for development, validation and routine control of a sterilization process for medical devices" and GB/T 18279.2-2015 "Sterilization of health care products - Part 2.Guidance on the application of GB 18279.1". In addition to structural adjustments and editorial changes, the main technical changes are as follows.

- Added instructions for the application of this document in health care facility (see

1.1 of this Edition);

- Added some terms (see 3.10, 3.38, 3.43, 3.57 of this Edition);
- Deleted some terms (see 3.19 of GB 18279.1-2015 and 3.1 of GB/T 18279.2-2015);
- Modified the requirements for the quality management system (see 4.1, 4.2, 4.3 of this Edition; 4.1, 4.2, 4.3 of GB 18279.1-2015);
- Modified the requirements for sterilizing agent (see 5.1, 5.2, 5.5 of this Edition; 5.1, 5.4 of GB 18279.1-2015);
- Added an overview of process and equipment characteristics (see 6.1 of this Edition);
- Modified the requirements for process characteristics (see 6.2 of this Edition; 6.1 of GB 18279.1-2015);
- Added the purpose and content of product definition (see 7.1.1, 7.1.5 of this Edition);
- Deleted the requirements for the most difficult to sterilize location (see 7.1.3 of GB 18279.1-2015);
- Added the purpose of process definition (see 8.1 of this Edition);
- Added general rules for confirmation (see 9.1 of this Edition);
- Added the requirements for installation qualification (see 9.2.1.3, 9.2.2.3, 9.2.2.4,

9.2.2.6 of this Edition);

- Added performance qualification requirements (see 9.4.1.1, 9.4.1.5, 9.4.1.6 of this Edition);
- Changed the requirements for performance qualification (see 9.4.1.8 of this Edition;

9.3 of GB 18279.1-2015);

- Added requirements for microbial performance qualification (see 9.4.2.5, 9.4.2.6,

9.4.3.2 of this Edition);

- Added parameters that shall be specified in the validation report (see 9.5.4 of this Edition);

- Added the objectives and requirements of routine monitoring (see 10.1, 10.2, 10.3 of this Edition);
- Changed the requirements for product release (see 11.2, 11.3, 11.4 of this Edition; Chapter 11 of GB 18279.1-2015);
- Changed the requalification requirements (see 12.3.1, 12.3.3 of this Edition; 12.3 of GB 18279.1-2015);
- Added requirements for change assessment (see 12.4.2, 12.4.6 of this Edition);
- Added the content of equivalence evaluation (see 12.5 of this Edition);
- Deleted the description of the procedures and calculation methods for the biological indicator/bioburden method (see A.2 and A.3 of GB 18279.1-2015);
- Changed the procedure of the overkill approach (see B.2 of this Edition; B.2 of GB 18279.1-2015);
- Changed the number of sensors and biological indicators (see Table C.1 and Table C.3 of this Edition; Table C.1 and Table C.3 of GB 18279.1-2015);
- Added content related to single batch release (see Annex E of this Edition).

The modification of this document adopted ISO 11135:2014 "Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices".

The technical differences between this document and ISO 11135:2014 and their reasons are as follows.

- Changed the description of the requirements for health care facility in the scope (see 1.1) to avoid conflicts between the mandatory requirements of the standard and the requirements of the regulations;
- Deleted the term "medical device" (see 3.21 of ISO 11135:2014) to avoid conflict with Chinese regulations;
- Changed the terminology of "spore-log-reduction" (see 3.41 of this Edition) to make it easier to understand;
- Deleted the exception for analytical (if used) process variable control (see 6.2.5 of

ISO 11135:2014) to standardize the process control requirements;

- Deleted the specification of the method for proving that the bioburden resistance is less than the resistance of the biological indicator in the overkill approach (see B.1.4 of ISO 11135:2014) to avoid limiting the application of the standard;
- Changed the references to other international standards in 4.1.2, 4.3.1, 4.3.2, 4.3.3, 4.4, 7.3.2, 8.9, 11.3, 11.4, and E.1 to notes to suit China's national conditions.

The following editorial changes were made to this document.

- The amendments to ISO 11135:2014/Amd.1:2018 were incorporated. The outer
- Deleted the note in 1.2.2 to adapt to China's national conditions;
- Used YY/T 0287-2017 to replace ISO 13485:2016 to adapt to China's national conditions;
- Moved the note referring to Annex E in 11.4 into the main text to be consistent with the normative Annex E;
- Simplified the description of A.2 to make the standard terms clearer;
- Added management standards for health care institutions for reference in applicable guidelines (see note to D.4.2.2).
- Added two notes in D.5.5.1 to better describe the combustion and explosion of ethylene oxide;
- Changed the interpretation of D.12.5 to refer to YY/T 1268 to make the standard content easier to understand.

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 document was proposed by and shall be under the jurisdiction of State Administration for Market Regulation.

Versions of standard substituted by this document are.

- It was first published in 2000 as GB 18279-2000;
- It was first revised in 2015 as GB 18279.1-2015 and GB/T 18279.2-2015;