

ICS 11.080.01
CCS C 47



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

GB/T 47143-2026

**Sterilization of health care products - Low temperature vaporized
hydrogen peroxide - Requirements for the development, validation and
routine control of a sterilization process for medical devices**

医疗产品灭菌 低温汽化过氧化氢 医疗器械灭菌过程的开发、确认和常规控制要求

(English Translation)

Issued on: January 28, 2026

Implemented on: August 1, 2027

Issued by: State Administration for Market Regulation

Table of Contents

Preface	
Introduction	
1 Scope	
2 Normative References	
3 Terms and Definitions	
4 Elements of a Quality Management System	
5 Characteristic description of sterilization factors	
6 Process and Equipment Characteristic Description	
7 Product Definition	
8 Process Definition	
9 Confirmed	
10 Routine monitoring and control	
11 Product sterilization and release 17.	
12 Maintain process effectiveness	
Appendix A (Normative) Factors to Consider When Selecting Microorganisms that Can Demonstrate Sterilization Effectiveness	
Appendix B (Normative) Method 1---Definition of Microbial Population Inactivation Process Based on Natural Conditions (Bioburden Method)	
Appendix C (Normative) Method 2 - Process Definition Based on Reference Microbial Inactivation and Understanding of Bioburden (Bioindicators/Bioburden Method)	
Appendix D (Normative) Method 3---Conserved Process Definition Based on Reference Microbial Inactivation (Overkill Method)	
Appendix E (Informative) Application Guidelines for this Document	
Appendix F (Informative) Example 41.Schematic diagram of VH ₂ O ₂ sterilization cycle	
Appendix G (Informative) Environmental Factors	
Appendix H (Informative) Justification for the Number of Temperature Sensors and Bioindicators	
Appendix I (Informative) VH ₂ O ₂ Factors	
Appendix J (Informative) Recommended Validation Tests	
Appendix K (Informative) Recommended Test Procedures	
Reference	

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is equivalent to ISO 22441:2022 "Sterilization of medical products - Low-temperature vaporization of hydrogen peroxide - Opening of sterilization processes for medical devices".

"Issuance, confirmation, and routine control requirements".

The following minimal editorial changes have been made to this document.

---The description of the ISO and IEC database URLs in the terms and definitions has been removed;

Note 2 was added in version 3.23.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Disinfection Technology and Equipment (SAC/TC200).

Introduction

This document specifies the development, validation, and routine control of sterilization processes using vaporized hydrogen peroxide (H₂O₂) aqueous solution as the sterilizing agent.

Control requirements. Vaporized hydrogen peroxide (VH₂O₂) sterilizers typically operate below 60°C and are mainly used for medical products that are not heat-resistant or moisture-sensitive.

Sterilization of moisture-sensitive medical devices can also be used for the sterilization of other reusable medical devices that have been proven to be compatible with the VH₂O₂ sterilization process.

The sterilizer operates automatically using preset cycles. Medical device manufacturers can also use VH₂O₂ sterilizers for sterilization in commercial production processes.

Sterile medical devices are medical devices free of surviving microorganisms. International standards specifying the validation and routine control requirements for the sterilization process must...

When sterile medical devices are required, efforts should be made to minimize incidental microbial contamination before sterilization. Even so, while meeting quality standards...

Medical devices manufactured under standard manufacturing conditions as required by quality management systems (such as ISO 13485) may contain microorganisms before sterilization.

Medical devices are not sterile. The purpose of sterilization is to inactivate microbial contaminants, thereby transforming non-sterile medical devices into sterile medical devices.

The kinetics of microbial inactivation by physical or chemical agents used for sterilization of medical devices can usually be expressed as the number of surviving microorganisms versus the amount of sterilizing agent released.

The exponential relationship between the degree of exposure is used to describe this; this necessarily means that, regardless of the treatment method applied, microorganisms will always have a certain probability of survival.

For a given treatment process, the survival probability depends on the number and resistance of the microorganisms, as well as the environment in which the microorganisms exist during the treatment.

Therefore, within the microbial population affected by sterilization treatment, the sterility of any medical device cannot be guaranteed, and the sterility of the treated population cannot be ensured.

Bacteria are defined based on the probability of the presence of live microorganisms on medical devices.

Exposure to a properly validated, precisely controlled sterilization process is not the only relevant factor providing reliable assurance regarding the processed medical products.

The medical devices are sterile and suitable in this respect for their intended use. Several factors should be considered, including.

- a) Microbial status of incoming materials or components;
- b) Validation and routine control of any cleaning and disinfection procedures for medical devices;
- c) Environmental control for the manufacturing, assembly, and packaging of medical devices;
- d) Control of sterilizers and processes;
- e) Control of personnel and their hygiene;
- f) Aseptic barrier systems, including any applicable protective packaging;
- g) Conditions for the transportation and storage of medical devices;

h) Medical device materials and designs in progress.

The types of contaminants on medical devices requiring sterilization vary, which can affect the efficiency of the sterilization process. Medical institutions use various types of medical devices...

Instruments, and medical devices sterilized according to the manufacturer's instructions (see ISO 17664-1), should be considered special cases. Despite the use of cleaning...

Although the process is streamlined, such medical devices may still contain various contaminating microorganisms and residual inorganic or organic pollutants. Therefore, cleaning during the manufacturing process is crucial.

Confirmation and control of the disinfection process are crucial.

Similar to other standardized low-temperature sterilization processes, such as ethylene oxide (ISO 11135) or low-temperature formaldehyde vapor (ISO 25424), physical and chemical sterilization methods are employed.

The parameters specified the VH₂O₂ sterilization process and were validated using physical, chemical, and microbiological methods.

Note 1: IEC 61010-1 and IEC 61010-2-040 describe operational safety specifications, which are not included in this document. IEC 60204-1 also...

Applicable.

Note 2: This document does not specify occupational safety requirements (see 1.2.4).

This document has two different application scenarios.

---For use by VH₂O₂ sterilizer manufacturers and users of VH₂O₂ sterilization processes in medical institutions;

---For manufacturers of VH₂O₂ sterilizers and users of VH₂O₂ sterilization processes in the production of medical products.

Medical product sterilization low-temperature vaporization hydrogen peroxide Development, validation and sterilization process for medical devices Conventional control requirements

1.1 Applicable

1.1.1

This document specifies the development and verification of a low-temperature sterilization process for medical devices using vaporized hydrogen peroxide (VH₂O₂) as the sterilizing agent.

Recognition, routine monitoring and control requirements.