

ICS 11.080.01
CCS C 47



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

GB/T 35267.5-2025

**Washer-disinfectors - Part 5: Performance requirements and
test method criteria for demonstrating cleaning efficacy**

清洗消毒器 第5部分：清洁效果的性能要求和测试方法

(English Translation)

Issued on: December 31, 2025

Implemented on: July 1, 2027

Issued by: State Administration for Market Regulation

Table of Contents

Preface
Introduction
1 Scope
2 Normative References
3 Terms and Definitions
4 Performance Requirements
5 Test Methods 6.
Appendix A (Informative) Examples of Test Pollutants
Appendix B (Normative) Performance Evaluation of Contaminants Based on Protein Tests
Appendix C (Informative) Examples of Test Methods for Detecting and Evaluating Residual Protein Contaminants
Appendix D (Informative) Example of a test method for detecting hemoglobin to assess cleaning effectiveness
Appendix E (Informative) Test Results Table 38.Performance Evaluation of Test Pollutants
References

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 Part 5 of GB/T 35267 "Cleaning and Disinfecting Equipment". GB/T 35267 has already published the following parts.

---Part 4: Endoscope Cleaning and Sterilization System;

---Part 5: Performance requirements and test methods for cleaning effectiveness.

This document is modified to adopt ISO 15883-5:2021 "Cleaning and disinfection equipment - Part 5: Performance requirements and test methods for cleaning effectiveness".

Compared with ISO 15883-5:2021, this document has undergone the following structural adjustments.

---B.3.1.1, B.3.2.1, B.7.6.1, B.8.1.1, and B.8.2.1 correspond to B.3.1, B.3.2, B.7.6, and B.8.1

of ISO 15883-5:2021.

The suspended section of B.8.2 will be followed by subsequent bar numbers;

---C.1.1, C.1.2, and C.1.3 correspond to C.1, C.1.1, and C.1.2 of ISO 15883-5:2021.

The technical differences between this document and ISO 15883-5:2021, and the reasons therefor, are as follows.

---ISO 10993-1 (see 5.5.2, 5.5.3) has been replaced with the normatively referenced GB/T 16886.1 to adapt to my country's technical requirements.

Add components to increase operability;

---ISO 10993-5 (see 5.5.3) has been replaced with the normatively referenced GB/T 16886.5 to adapt to my country's technical conditions, and the following has been added.

Operability;

---ISO 15883-1 has been replaced with the normatively referenced ISO 15883-1:2024 (see 4.1.3, 4.1.4, 4.4.3.1, 5.4.1), with the addition of...

Operability;

---The normative reference to ISO 15883-1 (see Chapter 3 of ISO 15883-5:2021) has been removed to accommodate my country's technical conditions;

---The supplier information in Tables B.2 and B.3 has been removed (see Appendix B) to increase operability.

The following editorial changes have been made to this document.

---The URL for the ISO 15883-5:2021 Chapter 3 ISO and IEC terminology database has been removed;

---ISO 15883-7 has been replaced by YY/T 0734.5 (see note 4.1.2) for informational purposes;

---ISO 15883-1 has been replaced with ISO 15883-1:2024 (see 4.3.1, 4.4.4, 5.2.3, 5.5.1, 5.5.3,...).

5.5.4);

---ISO 15883.4 has been replaced with GB/T 35267.4 (see 4.3.1) for informational reference;

---ISO 14971 has been replaced by GB/T 42062 (see note 4.4.1) which is used for informational purposes;

--- EN13018 has been replaced with GB/T 20967 (see 4.4.2), which is cited in the informational reference.

---ISO/IEC 17025 has been replaced with GB/T 27025 (see note 5.1.1) for informational purposes.

---ISO 11737-1 has been replaced by GB/T 19973.1 (see note 5.1.3.2) which is cited in the informational reference.

---Added the numbering of *Pseudomonas aeruginosa* and *Enterococcus faecalis* in CMCC and the introduction of CMCC (see Table A.1).

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

GB/T 35267 "Cleaning and Disinfecting Equipment" is a general and specific standard concerning cleaning and disinfecting equipment, aiming to provide standards for cleaning and disinfecting equipment and their accessories.

The regulations concerning the terms and definitions, general requirements, test methods, marking and instructions, packaging, transportation and storage of the components are proposed to be divided into 7 parts.

constitute.

---Part 1: General Requirements and Tests. The purpose is to provide general requirements and tests for cleaning and disinfection equipment.

---Part 2: Requirements and Testing for Cleaning and Sterilizing Equipment for Moist Heat Sterilization of Surgical and Anesthesia Instruments. The purpose is to provide requirements for...

Requirements and tests for cleaning and disinfection equipment used for moist heat disinfection of surgical and anesthetic instruments.

---Part 3: Requirements and Testing for Cleaning and Sterilizing Equipment for Moist Heat Disinfection of Human Waste Containers. The purpose is to provide guidelines for the use of cleaning and sterilizing equipment for human waste containers.

Requirements and tests for cleaning and disinfection equipment used for moist heat disinfection of waste containers.

---Part 4: Endoscope Cleaning and Sterilizing Equipment. The purpose is to provide requirements and testing guidelines for endoscope cleaning and sterilizing equipment.

---Part 5: Performance Requirements and Test Methods for Cleaning Effectiveness. The purpose is to provide test contaminants and methods for verifying cleaning effectiveness. method.

---Part 6: Requirements and Tests for Cleaning and Sterilizing Equipment for Moist Heat Sterilization of Non-invasive Medical Devices. The purpose is to provide...

Requirements and tests for cleaning and disinfection equipment used for moist heat disinfection of non-invasive medical devices.

---Part 7: Requirements and testing for cleaning and sterilizing equipment used for chemical disinfection of heat-sensitive non-invasive medical devices. Purpose the requirement is to provide requirements and testing for cleaning and disinfection equipment used for chemical disinfection of non-invasive medical devices that are not heat-resistant.

Cleaning and sterilizing equipment Part 5: Performance Requirements and Test Methods for Cleaning Effectiveness

1 Scope

This document specifies the procedures for testing the cleaning effectiveness of using cleaning and disinfection equipment and its accessories to clean reusable medical devices.

Experimental methods.

This document is applicable to testing the cleaning effectiveness of cleaning and sterilizing equipment.

This document does not apply to the manufacturing activities of manufacturers of reusable medical devices.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022,ISO 10993-1:2018,IDT) GB/T 16886.5 Biological evaluation of medical devices - Part 5: In vitro cytotoxicity tests (GB/T 16886.5-2017) ISO 10993-5:2009, IDT ISO 15883 (all parts) - Washer-disinfectors ISO 15883-1:2024 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests