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

GB/T 35267.4-2025

Washer-disinfectors - Part 4: Endoscope washer-disinfectors

清洗消毒器 第4部分：内镜清洗消毒器

(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 part 4 of GB/T 35267 "Washer-disinfectors". GB/T 35267 has been published in the following parts.

--- Part 4: Endoscope cleaning and disinfection equipment.

This document replaces GB/T 35267-2017 "Endoscope Cleaner-Disinfector". Compared with GB/T 35267-2017, except for structural adjustment and compilation in addition to logical changes, the main technical changes are as follows.

- Added some terms and definitions (see Chapter 3, Chapter 3 of the 2017 edition);
- Deleted "Structure and Working Conditions" (see Chapter 4 of the 2017 edition);
- Added "General" (see 4.1);
- Changed "detection system" to "leak test" and changed the relevant content (see 4.2, 5.1 of the 2017 edition);
- Changed the cleaning requirements (see 4.3, 5.3 of the 2017 edition);
- Changed the disinfection requirements (see 4.4, 5.4 of the 2017 edition);
- Changed the requirements for rinsing (rinsing after disinfection) (see 4.5, 5.5 of the 2017 edition);
- Added the requirement for drying the rinse water (see 4.6);
- Changed the drying requirements (see 4.7.1, 4.7.3, 5.6 of the 2017 edition);
- Changed the requirements for air filters (see 4.6.2, 5.9 of the 2017 edition);
- Changed the requirements for self-disinfection (see 4.8, 5.7 of the 2017 edition);
- Added requirements for water treatment equipment (see 4.9);
- Added requirements for materials---design, manufacturing and construction (see 5.1);
- Added requirements for equipment pipeline perfusion system (see 5.2);
- Added requirements for ventilation and drainage systems (see 5.3);
- Added temperature control requirements (see 5.4);
- Added requirements for chemical agents (see 5.5);
- Added requirements for process validation (if any) (see 5.6);
- Changed the requirements for the measurement system (see 5.7, 5.15 of the 2017 edition);
- The test method has been changed (see Chapter 6, Chapter 7, Chapter 6 of the 2017 edition);
- Changed the information that the manufacturer should provide (see Chapter 8, 5.29 of the 2017 edition);
- Changed the marking and instruction manual (see Chapter 9, Chapter 7 of the 2017

edition);

- Changed the provisions on packaging, transportation and storage (see Chapter 10, Chapter 8 of the 2017 edition);
- Changed the cleaning effect test (see Appendix C, Appendix A of the 2017 edition);
- Added microbial contamination test for rinsing water after disinfection (see Appendix D);
- Added microbiological evaluation methods for liquid delivery system disinfection (see Appendix E);
- Added the microbial quantity test for the final rinse water treatment device (see Appendix F);
- Added "Establishing an endoscope type test group" (see Appendix H).

This document is modified to adopt ISO 15883-4:2018 "Washer-disinfectors - Part 4: Washer-disinfectors for chemical disinfection of heat-sensitive endoscopes".

Requirements and Tests for Poison Devices.

Compared with ISO 15883-4:2018, this document has many structural adjustments. The structural number changes between the two documents are shown in the table below.

See Appendix A for the table.

This document has many technical differences compared to ISO 15883-4:2018.

A list of these technical differences and their reasons is given in Appendix B.

The following editorial changes were made to this document.

- In order to coordinate with the existing standards, the name of the standard is changed to "Washer-disinfector Part 4: Endoscope washer-disinfector";
- Deleted the following from Chapter 1 "Scope" of ISO 15883-4:2018: "Also specifies type testing, engineering testing, verification (installation, first methods required for operation and performance qualification at installation), routine control and monitoring, and requalification after periodic and necessary maintenance, Instrumentation and Instructions";
- Deleted Note 1 in Chapter 1 "Scope" of ISO 15883-4:2018;
- Deleted 4.1.1c) and 4.1.1f) in ISO 15883-4:2018);
- Adjust the two sub-images in Figure 2 into two separate images;
- Deleted Annex A (informative) "Overview of activities covered by this document" in ISO 15883-4:2018;
- Deleted Appendix F (informative) "Additional instructions for microbiological testing of chemical disinfection processes" in ISO 15883-4:2018;

--- Deleted the section number and title of Appendix G (informative) "G.1 Specification drawings" in ISO 15883-4:2018.

Introduction

GB/T 35267 "Cleaning Disinfectors" is a general and specific standard for cleaning disinfectors, aiming to provide cleaning disinfectors and their accessories.

The relevant provisions of the parts, such as terms and definitions, general requirements, test methods, marking and instructions, packaging, transportation and storage, are planned to consist of 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 tests for cleaning and disinfecting equipment for moist heat disinfection of surgical and anesthesia instruments.

Requirements and testing for washer-disinfectors for moist heat disinfection of, for example, surgical and anaesthesia instruments.

--- Part 3: Requirements and tests for washer-disinfectors for moist heat disinfection of human waste containers.

Requirements and testing for washer-disinfectors for moist heat disinfection of bulk waste containers.

--- Part 4: Endoscope cleaning and disinfection equipment. The purpose is to provide requirements and tests for endoscope cleaning and disinfection equipment.

--- Part 5: Performance requirements and test methods for cleaning effect. The purpose is to provide performance requirements for cleaning effect of cleaning disinfectors and testing methods.

--- Part 6: Requirements and tests for cleaning and disinfecting equipment for wet heat disinfection of non-invasive medical devices. The purpose is to provide Requirements and testing for washer-disinfectors for moist heat disinfection of non-invasive and other medical devices.

--- Part 7: Requirements and tests for cleaning and disinfecting equipment for chemical disinfection of non-invasive medical devices that are not heat resistant. Purpose to provide requirements and tests for cleaning and disinfecting equipment for chemical disinfection of non-invasive medical devices that are not heat resistant.

The washer-disinfectors detailed in this document are intended to process instruments that can be immersed in water or aqueous solutions.