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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1957-2025

Vacuum washer-disinfectors

负压清洗消毒器

Issued on: February 26, 2025 **Implemented on: September 1, 2026**

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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. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Disinfection Technology and Equipment (SAC/TC200). This document was drafted by: Shandong Xinhua Medical Device Co., Ltd., Guangdong Medical Device Quality Supervision and Inspection Institute, Guangzhou Jihao Medical Medical Technology Co., Ltd., Beijing Baixiang New Technology Co., Ltd., and Peking Union Medical College Hospital, Chinese Academy of Medical Sciences. The main drafters of this document. Zhang Longlong, Liao Huier, Li Yadong, Tang Xiaowei, Sun Mingqiang, Zhang Qing, Zhou Yuxin, Li Lin, Xia Yi. Negative pressure cleaning disinfector

1 Scope

YY/T 1957 is the product standard for the negative pressure washer-disinfector used in hospital sterile services. It specifies the performance requirements for negative pressure cleaning and disinfection equipment and describes the corresponding test methods, applying to washer-disinfectors that operate under negative pressure. Drawing a vacuum during the cycle helps liquid reach the inside of narrow lumens, which is precisely where conventional washers fail and where the reprocessing of endoscopes and cannulated instruments succeeds or does not. The standard's job is to make that cleaning performance measurable rather than assumed. It takes effect on 1 September 2026. For a manufacturer or an importer of washer-disinfectors for the Chinese market, this is the standard the performance testing follows.

This document specifies the performance requirements for negative pressure

washer-disinfectors and describes the corresponding test methods. This document is applicable to cleaning and disinfection equipment with negative pressure cleaning function and in compliance with the applicable clauses in YY/T 0734.1 and the requirements of the corresponding special standards. Poison weapon. This document does not apply to washer-disinfectors that do not have negative pressure cleaning function.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB 8599-2023 Technical requirements for large pressure steam sterilizers

YY/T 0734.1-2018 Washer-disinfector Part

3 Terms and definitions

The terms and definitions defined in YY/T 0734.1-2018 and the following apply to this document.

3.1 A0 value The equivalent time measured in seconds during moist heat disinfection at 80°C is taken as 10°C. [Source: YY/T 0734.1-2018, 3.1]

3.2 Bubble Generator A device that introduces external filtered air into the cavity and evenly generates bubbles in the water during the liquid phase pulsating cleaning process.

3.3 Bubble washing The cleaning method utilizes the pressure difference between the inside and outside of the cavity and generates bubbles through a bubble generating device to achieve load cleaning.

3.4 Chamber Negative pressure washer-disinfector A device that handles loads and withstands negative pressure environments.

3.5 The water in the cavity is pumped to a boiling state under negative pressure at a set temperature, and the filtered air from the outside is returned to the liquid surface through the gas phase. The empty pipe is introduced into the cavity and quickly re-pressurized, so that the water inside the cavity flows back and forth many times to achieve the purpose of stripping pollutants. Cleaning method.

3.6 Hot air drying hotairdrying A method that uses flowing hot air to increase the surface temperature of the load and remove residual moisture.