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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 47144-2026

Requirements for the development, validation and routine control of cleaning processes for medical devices

医疗器械清洁过程的开发、确认和常规控制的要求

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1 Scope

GB/T 47144-2026 is the Chinese national standard covering cleaning a medical device before it is sterilised - sterilisation does not work through soil, so the cleaning process has to be developed against a defined worst-case contamination, validated with recovery studies and then controlled in routine. First edition, in force from 1 August 2027, under the National Medical Products Administration. It was issued on 28 January 2026 and takes effect on 1 August 2027, as a first edition. The document is under the responsibility of the National Medical Products Administration. This page is published from the official record of the 2026 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document specifies the requirements for the development, validation, and routine control of cleaning processes for medical devices. This document applies to the cleaning process during the production and use of medical devices, medical institutions, other medical products requiring cleaning, and manual cleaning. Follow the cleaning process as a reference. This document does not apply to.

---Disposable medical devices supplied to patients in a ready-to-use state;

---Textiles used in patient sterile hood systems or surgical gowns; or

---Instruments that may come into contact with prions, such as instruments that may be contaminated with infectious spongiform encephalopathy (TSE) virus.

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 16886.17 Biological evaluation of medical devices - Part

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 chamber The part of the equipment that is under processing load. [Source: GB/T 19971-2026, 3.37, with modifications]

3.2 cleaning Remove contaminants to the extent necessary for further processing or intended use. [Source: GB/T 19971-2026, 3.47]

3.3 Cleaning agent A physical or chemical entity, or a combination of entities, that enables an item to achieve a cleaning effect. [Source: GB/T 19971-2026, 3.48]

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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. 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). This document was drafted by: Shandong Xinhua Medical Instrument Co., Ltd., Guangdong Provincial Institute of Medical Device Quality Supervision and Inspection, and the Chinese Academy of Medical Sciences. The college, Peking Union Medical College Hospital, Changshu Rongrui Sterilization Technology Co., Ltd., Zhongguancun International Medical Testing and Certification Technology Co., Ltd., and

Chongqing Medical Device... Medical Device Quality Inspection Center, Diekang (Shanghai) Trading Co., Ltd., Mairun Medical Technology (Shaoxing) Co., Ltd., and Beiliman Medical Equipment (Shanghai) Co., Ltd. Limited Liability Company, Stereo (Shanghai) Trading Co., Ltd., Maikewei Medical Equipment (Suzhou) Co., Ltd., Hebei Rongfeng Disinfection Equipment Co., Ltd. Olympus (Beijing) Sales & Service Co., Ltd. Shanghai Branch, Shandong Ande Medical Supplies Co., Ltd., Xinhua Surgical Instruments Co., Ltd. company. The main drafters of this document are. Zhang Longlong, Lin Manting, Tu Rong, Hu Changming, Zhang Qing, Zhou Ping, Su Yuxin, Guo Jing, Zhu Yibing, Wu Shaohai, and Zhou Zhilong. Xu Weixiong, Wang Yimin, Zhang Jie, Wang Yizhen, Zhang Liwen, Chen Huahua, Chen Jiansheng, Wang Kui, Sun Mingqiang, Huang Yanhong.

Medical device manufacturers are responsible for the cleanability of the devices they produce that require cleaning, and must guarantee that the devices have reliable and repeatable cleaning capabilities. Cleaning method. Cleaning is typically considered a critical or special process in medical device manufacturing. The purpose of cleaning is to remove... Medical devices are susceptible to surface contaminants, processing aids, and certain microorganisms during the manufacturing process, which must be addressed to ensure the smooth operation of the medical devices. Further processing is required to ensure the safety and effectiveness of the product upon delivery. The effectiveness of the cleaning process is assessed by evaluating cleaning process parameters (such as cleaning time). The composition, concentration, and temperature of the chemical agents (such as time and temperature) are confirmed, and the performance and cleaning effect of the cleaning equipment are confirmed and monitored regularly. For reusable medical devices, manufacturers must provide validated cleaning process instructions. More importantly, the cleaning process must be validated. Organizations handling medical devices can effectively clean them before sterilization and/or disinfection (if applicable). This document aims to provide medical device manufacturers with requirements for the development, validation, and routine control of medical device cleaning processes. Furthermore, this document... It also provides information for developing cleaning plans, selecting test contaminants, and determining acceptance criteria. Therefore, the requirements described in this document apply to cleaning processes intended for removing contaminants attached to medical devices to ensure cleaning results. Reliable and reproducible. The development, validation, and routine control of the cleaning process involves several disjointed but related activities, such as calibration, maintenance, product definition, and process control. The process includes definition, installation qualification, operational qualification, and performance qualification. Individuals or organizations can selectively implement these as needed; Appendix A provides details for each activity. The party responsible for the action. Development, validation, and standardization of medical device cleaning processes Control requirements

17 Toxicological risk assessment of medical device components

GB/T 19022 Measurement Management System - Requirements for Measurement Processes and Measuring Equipment

GB/T 42061-2022 Medical Device Quality Management System - Regulatory Requirements

GB 42125.11 Safety requirements for electrical equipment for measuring, controlling and laboratory use - Part

11.Sterilization of medical materials Special requirements for cleaning and sterilizing equipment