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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 47333-2026

Single-use swabs for the collection of clinical specimens

一次性使用采样拭子

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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. 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 Medical Protective Equipment Standardization Working Group (SAC/SWG30). This document was drafted by: Shandong Provincial Institute for Medical Device and Pharmaceutical Packaging Inspection, Chengdu Ruiqi Medical Technology Co., Ltd., and Fujian... Provincial Institute for Food and Drug Quality Inspection, Beijing Municipal Institute for Medical Device Inspection (Beijing Municipal Medical Biological Protective Equipment Inspection and Research Center) China Resources Medical Supplies (Henan) Co., Ltd., Henan Tuoren Medical Technology Co., Ltd., Hangzhou Yiguoren Biotechnology Co., Ltd., and the People's Bank of China The Third Medical Center of the PLA General Hospital. The main drafters of this document are. Liu Bin, Liu Xiaoshuai, Zhang Luwen, Wang Xiaomei, Li Xiang, Li Ying, Li Chengzhi, Duan Shuxia, Meng Qiang, Wang Haiying, and Zhao Aijing. Zhou Xiaoshuang, Dong Chuanjun, Huang Yongfu, Zhou Yiling.

The main purpose of this document is to standardize the product quality of disposable sampling swabs (hereinafter referred to as swabs), from aspects such as design, materials, and performance. This document evaluates swabs from multiple dimensions, referencing relevant literature to provide a more comprehensive assessment and ensure their safety and efficacy. Effectiveness. Swabs are a key sampling tool in clinical testing, and their quality directly affects the accuracy of subsequent clinical test results. Depending on the material of the sampling head, swabs can be classified into polyester fiber, nylon synthetic short fiber, cotton fiber, polyurethane sponge, and calcium alginate. Swabs can take various forms, including cotton swabs; depending on the intended clinical sample, they can be categorized as nasal swabs, pharyngeal swabs, vaginal swabs, cervical swabs, anal swabs, and urethral swabs. The pole is generally made of materials such as plastic, metal, and

wood. To avoid the potential risk of swabs causing harm to patients, the safety of swabs must be fully considered. The safety of swabs is mainly reflected in their production... In terms of product design, structure, and materials, it is adapted to different application scenarios and sampling locations. In addition to safety, the effectiveness of the swabs must also be considered. The effectiveness of the swabs is reflected in their sample collection ability, elution ability, and ability to handle subsequent samples. Interference from clinical testing. Swabs with different sampling heads have varying abilities to collect and elute analytes. Appendix B provides guidelines for swab collection and... Elution efficiency (recovery rate) research guidelines, with manufacturer data provided when necessary to assist clinical testing laboratories in selecting appropriate products. Sampling. The manufacturing processes for the heads are diverse, including gluing, winding, and heat sealing. The materials, processes, and production environment used can all potentially affect subsequent clinical testing. To address interference, Appendix C provides guidelines for swab interference testing. When questionable clinical results occur, manufacturers should provide relevant study data. This is to help eliminate interference in clinical practice. Disposable sampling swabs

1 Scope

GB/T 47333-2026 is the Chinese national standard covering the sampling swab - the tip material and its release of what it collected, the shaft and its breakpoint, the sterility and the packaging, on a product the world discovered it needed by the billion. First edition, in force from 1 April 2027. It was issued on 31 March 2026 and takes effect on 1 April 2027, as a first edition. The document is under the responsibility of the Standardization Administration of China. 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.

YY/T 0466.1 Symbols for medical devices used to provide information to manufacturers - Part

1.General requirements Pharmacopoeia of the People's Republic of China (2025 Edition, Part IV)

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 6682 Specifications and test methods for water used in analytical laboratories

GB/T 14233.1-2022 Medical infusion, transfusion and injection equipment test methods - Part

3 Microbiological test methods

GB/T 16886.1 Biological evaluation of medical devices - Part

4 Structural Composition

4.1 Structure A typical swab structure may include a sampling head and a swab handle (with or without a break point). Some swabs may also have additional components (such as a handle, protective cover, etc.). set).

4.2 Schematic Diagram The typical structure of a swab is shown in Figures 1, 2 and 3.