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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 46302-2025

Automatic sample processing system for medical use

医用全自动样本处理系统

Issued on: October 5, 2025 **Implemented on: November 1, 2026**

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Standardization Administration of the PRC

Table of Contents

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 Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Beijing Institute for Medical Device Testing (Beijing Medical Biological Protective Equipment Testing and Research Center), China Food... Drug Testing Institute, Jiangsu Provincial Medical Device Testing Institute, Beijing Tiantan Hospital affiliated to Capital Medical University, Shenzhen Yahuilong Biotechnology Co., Ltd. Limited Liability Company, Shandong Boke Biotechnology Industry Co., Ltd., Hitachi Diagnostics Products (Shanghai) Co., Ltd., The Second Affiliated Hospital of Zhejiang University School of Medicine Institute, Antu Laboratory Instruments (Zhengzhou) Co., Ltd., Beijing BGI Genomics Co., Ltd., Dirui Medical Technology Co., Ltd. Mike Medical Electronics Co., Ltd., Abbott Trading (Shanghai) Co., Ltd., Beckman Coulter Trading (China) Co., Ltd., Siemens Medical Center Disconnect Products (Shanghai) Co., Ltd., Roche Diagnostics Products (Shanghai) Co., Ltd., Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Shenzhen New Industries Biomedical Engineering Co., Ltd. and Changsha Maidec Intelligent Technology Co., Ltd. The main drafters of this document are. Zhao Bingfeng, Wang Yue, Zhou Qiyang, Zhang Guojun, Xiao Yujin, Xie Qinghua, Cheng Qing, Tao Zhihua, Liu Cong, and Cui Xianghua. Huo Ran, Wang Yuanyuan, Wu Xiaojun, Zhou Jing, Wang Kai, Wang Rongfei, Li Xuerong, Yin Li, Song Renjun, Li Shengmin, Sun Li. Fully Automated Medical Sample Processing System

1 Scope

GB/T 46302-2025 is the Chinese national standard covering the laboratory automation line - the sorting, centrifuging, decapping, aliquoting and archiving of tubes without a hand touching them, the throughput and the tracking of every tube, the carry-over between samples, and the safety of an operator working near it. First edition, under the National Medical Products Administration. In force from 1 November 2026. Issued on 5 October 2025, it takes effect on 1 November 2026.

This document specifies the requirements, labeling, instructions for use, packaging, storage, and transportation of fully automated medical sample processing systems, and describes... The corresponding experimental methods. This document applies to clinical samples that are connected to medical testing modules using automated track and information network technologies before and after testing. Processing system. This document does not apply to equipment in clinical laboratory analytical instruments that have precise reagent and sample dispensing functions before analysis.

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 191 Pictorial Symbols for Packaging and Storage

GB/T 14710 Environmental requirements and test methods for medical electrical appliances

GB/T 18268.1 Electromagnetic compatibility requirements for electrical equipment for measuring, control and laboratory use - Part

3 Terms and Definitions

This document does not contain any terms or definitions that need to be defined.

4.General Requirements A fully automated medical sample processing system refers to a system that connects medical testing modules through automated tracks and information network technology to form a complete system. A complete detection system. A fully automated medical sample processing system typically consists of a sample input module, a centrifugation module, a capping module, a dispensing module, and a track module. It consists of modules such as block, interface module, capping module, sample output module, sample storage module, and software, but does not include sample reaction or signal acquisition and analysis. Modules can be freely combined and used by the manufacturer according to usage requirements. This document only covers the sample processing module in the integrated detection system. For modules and testing functions,

please refer to relevant product standards. Modules or products not listed in this document should be identified by the manufacturer based on product characteristics and usage. The requirements should be specified accordingly.

5 Special requirements for laboratory centrifuges Require

GB/T 42125.14 Safety requirements for electrical equipment for measuring, controlling and laboratory use - Part

14.Laboratory analytical and other applications Special requirements for automatic and semi-automatic equipment

YY/T 0086-2020 Medical Refrigerator

YY/T 0657-2017 Medical Centrifuges