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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1902-2024

Medical plasma quick freezer

医用血浆速冻机

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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 is required. 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 was prepared by the National Technical Committee for Safety Standardization of Measurement, Control and Laboratory Electrical Equipment, Medical Equipment Subcommittee (SAC/TC338/SC1) is responsible for this matter. This document was drafted by: Liaoning Medical Device Inspection and Testing Institute, Beijing Medical Device Inspection Institute (Beijing Medical Bioprotection Institute Equipment Inspection Research Center), Anhui Food and Drug Inspection Institute, Shandong Medical Device and Drug Packaging Inspection Institute, Peking University Third Hospital, Qingdao Haier Biomedical Co., Ltd., Wuhan Beso Medical Equipment Co., Ltd., Zhengzhou Feilong Medical Equipment Co., Ltd., Shansongyang Biotechnology (Dalian) Co., Ltd. and Zhongke Meiling Cryogenic Technology Co., Ltd. The main drafters of this document are. Yang Yan, Wang Bo, Feng Lei, Zhao Yongxin, Zhang Ke, Wang Dong, Jiao Qiang, Huang Yanchun, Ye Xiaocan, Chen Haitao, Jin Can, Shen Yan Kui, Liu Fazhu, Qu Yaohui, Yuan Shuntao, Yao Benhu, and Su Meihua. Medical plasma quick freezing machine

1 Scope

YY/T 1902 is the product standard for the medical plasma quick freezer used in blood services. It specifies the product classification and the requirements for plasma quick freezing machines and describes the corresponding test methods. Speed is the whole point: fresh frozen plasma retains its labile coagulation factors, factor VIII above all, only if the unit is frozen to its core quickly enough after separation, and a freezer that reaches

temperature slowly produces a product that is frozen but no longer fresh frozen plasma in any meaningful sense. Freezing rate, uniformity across the load and temperature verification are therefore the requirements. The 2024 edition takes effect on 20 July 2025. For a manufacturer or an importer serving Chinese blood centres, this is the governing standard.

This document specifies the product classification and requirements of medical plasma quick freezers (hereinafter referred to as quick freezers) and describes the corresponding test methods. This document applies to medical plasma quick freezing machines. This document does not apply to quick freezers using heat transfer methods other than clamp-on and air-cooled types.

2 Normative references

The contents of the following documents constitute the 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 4793.1 Safety requirements for electrical equipment for measurement, control and laboratory use Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Medical equipment used to quickly freeze plasma products.

3.2 A heat conduction quick freezer in which the cold plate (3.13) contacts the plasma bag by clamping.

3.3 A thermal convection quick freezer that uses forced air cooling convection to quickly freeze plasma products.

3.4 Overall quick freezer A quick freezer with all components (including refrigeration device and automatic control device, etc.) assembled in one.

3.5 Split quick freezer split quick freezer The quick freezer consists of two parts. indoor and outdoor.

3.6 Quick freezer for plasma products, accessed through the front door.

3.7 A quick freezer for placing and removing plasma products through a top door or lid.