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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1945-2025

Blood thawing device

血液融化设备

Issued on: June 18, 2025 **Implemented on: July 1, 2027**

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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 was prepared by the Medical Equipment Subcommittee of the National Technical Committee on Standardization of Measurement, Control and Laboratory Electrical Equipment Safety. (SAC/TC338/SC1) is under its jurisdiction. This document was drafted by: Shandong Weigao Group Medical Polymer Products Co., Ltd., and Beijing Institute for Medical Device Testing (Beijing). (Municipal Medical Biological Protective Equipment Testing and Research Center), Shandong Provincial Food and Drug Evaluation and Inspection Center, Shandong Provincial Medical Device and Drug Packaging Inspection Center Research Institute, Shandong Provincial Blood Center, Suzhou Medical Instrument Factory, Wuhan Beso Medical Device Co., Ltd., Liaoning Provincial Medical Device Testing and Inspection Center The institute, Shandong Boke Scientific Instruments Co., Ltd., Qingdao Haier Biomedical Co., Ltd., and Shandong Xinhua Medical Instruments Co., Ltd. The main drafters of this document are. Yue Fangchao, Huang Yanchun, Mou Pengtao, Li Guoyong, He Weidong, Zhang Yiwei, Jin Can, Wang Bo, Wei Guosheng, and Li Weiyang. Liu Xincheng, Chen Haitao, Guo Chenghu. Blood melting equipment

1 Scope

YY/T 1945 is the product standard for the blood thawing device used in transfusion services. It specifies the requirements for blood thawing equipment and describes the corresponding test methods, and it applies to equipment using the constant-temperature water bath thawing principle. Thawing plasma or cryoprecipitate is a narrow operation: too slow and the component degrades, too warm and proteins denature, and a water bath adds

a contamination route that dry methods do not have, so temperature control and the integrity of the bag during the cycle are what the standard has to pin down. It takes effect on 1 July 2027. For a manufacturer or an importer of plasma thawers serving Chinese blood banks and hospitals, this is the standard the registration testing follows.

This document specifies the requirements for blood melting equipment (hereinafter referred to as melting equipment) and describes the corresponding test methods. This document applies to melting equipment that uses the principle of constant temperature water thawing. This document does not apply to plasma melting equipment used for preparing cryoprecipitate or melting equipment using microwave ovens, radio frequency methods, or dry hot air methods.

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 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

The following terms and definitions apply to this document.

3.1 Plastic blood bags containing frozen blood components are placed in a thawing area, where the frozen blood components are thawed using constant-temperature water. equipment.

3.2 Thawing Area The area specified by the manufacturer for storing plastic blood bags containing frozen blood components.

3.3 bloodcomponents Blood products made by separating one or more blood components from whole blood under certain conditions and using specific methods, and apheresis products. A general term for blood division. [Source: GB 18469-2012, 3.4]

4.1 Working conditions

4.1.1 Ambient temperature. 10°C~30°C.

4.1.2 Relative humidity. not greater than 80%.