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

YY 1413-2016

Centrifugal blood component separation device

离心式血液成分分离设备

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Foreword

The technical content of this standard is mandatory. This standard is drafted in accordance with the rules given in GB/T 1.1-2009. Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This standard is proposed by the State Food and Drug Administration. This standard by the National Medical Extracorporeal Circulation Equipment Standardization Technical Committee (SAC/TC158) centralized. The drafting of this standard. the State Food and Drug Administration Guangzhou Medical Device Quality Supervision and Inspection Center, Sichuan Nangeer Biomedical Co., Ltd., Tyler Bobby Special Medical Products Trading (Shanghai) Co., Ltd. The main drafters of this standard. Wu Shaohai, He Min, Liu Xiangrong, Wang Peng, Zhang Yujie. Centrifugal blood component separation equipment

1 Scope

YY 1413 is the mandatory Chinese standard for centrifugal blood component separators, the apheresis machines that draw blood from a donor or patient, spin out one component and return the rest. It sets the requirements such equipment has to meet and the test methods that verify them, covering the separation performance and the purity and yield of the collected component, the volumes handled and the limits on extracorporeal volume, the anticoagulant management, and the alarms and protections against air, pressure and disconnection. The person connected is often a healthy volunteer donor, which sets the tolerance for risk lower than for a patient device. Apheresis underpins the Chinese platelet supply. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the terms and definitions of centrifugal blood component separation equipment (hereinafter referred to as equipment), requirements, test methods, signs, use Brochures and packaging, transportation, storage. This standard applies to the use of disposable supplies to connect blood donors, can simultaneously achieve blood collection, centrifugal blood composition separation, Return equipment. This standard does not apply to the following products. - equipment or consumables for non-centrifugal blood separation, such as extrusion or membrane separation (eg separation or adsorption, etc.) Or supplies;

- with the equipment used in the pipeline, centrifugal cup, centrifugal bags and other supplies annex;
- autologous blood recovery equipment;
- Medical centrifuge;
- only the blood of the blood bag to deal with the equipment.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document.

GB/T 191 packaging and storage icon Medical electrical equipment - Part 1. General requirements for safety

GB 9706.1 General specification for industrial product brochures

GB/T 9969-2008 Environmental requirements and test methods for medical appliances

GB/T 14710-2009

GB 18469 Whole blood and ingredients Blood quality requirements

YY/T 0466.1 Symbols for use in medical device labeling and information for medical devices - Part 1. General requirements

YY 0709 Medical electrical equipment - Part 1-8. Safety requirements for general requirements. General requirements Medical electrical equipment and medical care Test and guidance for alarm systems in electrical systems

3 Terms and definitions

GB 18469 and GB 9706.1 and the following terms and definitions apply to this document.

3.1 Centrifugal blood component separation centrifugalseparationofthebloodcomponents
According to the difference in the proportion of blood components, the use of centrifugal principle to achieve the separation of blood components.

3.2 Donor donor Blood providers can refer to blood donors or patients.

3.3 Blood component product bloodcomponentproducts Blood is collected after the separation of blood components.