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File No.: 9936-2002



**PROFESSIONAL STANDARD OF THE PEOPLE'S  
REPUBLIC OF CHINA**

**中华人民共和国医药行业标准**

YY 0326.1-2002

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**Plasmapheresis centrifuge apparatus for single  
use—Part 1: Centrifuge bowl  
一次性使用离心式血浆分离器  
第 1 部分：血浆分离杯**

Issued on January 07, 2002

Implemented on April 01, 2002

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Issued by China Food and Drug Administration

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## **Foreword**

The disposable plasmapheresis centrifuge apparatus is composed of centrifuge bowl, plasma pipe and hemostix regulated in YY 0328, and is used with the centrifugal automatic plasma collection machine to collect, separate the human plasma and transfuse the blood.

The general title of YY 0326 is the disposable plasmapheresis centrifuge apparatus, which includes the following parts:

Part 1: Centrifuge bowl

Part 2: Plasma pipe

Annex A, Annex B, Annex C and Annex D of in this standard are the standard annex.

This standard is proposed by the State Drug Administration.

This standard is under the jurisdiction of National Standardization Technical Committee of Medical Infusion Apparatus.

The drafting units of this standard: Shanghai Blood Center, Jinan Medical Device Quality Supervision and Inspection Center of State Drug Administration.

Units participating in draft of this standard: Shanghai Xili Medical Co., Ltd., Sichuang Nangeer Medical Appliances Co., Ltd., Xi'an Zhengyuan Polymer Products Co., Ltd.

Main drafters of this standard: Pan Lihua, You Shaohua, Sun Jianfang, Shi Yanping, Zhang Jiang, Jiang Yueqin, Lu Ansong.

# **Medical industry standard of People's Republic of China**

## **Plasmapheresis centrifuge apparatus for single use -**

### **Part 1: Centrifuge bowl**

#### **1 Scope**

This standard regulates the requirements of the component of plasma pipe of the disposable plasmapheresis centrifuge apparatus (hereinafter referred to as the pipe" to ensure that the centrifugal automatic plasma collection machine is suitable to the centrifuge bowl and blood collection apparatus.

#### **2 Normative references**

The articles contained in the following documents have become this standard when they are quoted herein. For the dated documents so quoted, all the modifications or revisions made thereafter shall not be applicable to this standard. For the undated documents so quoted, the latest editions shall be applicable to this standard.

GB/T 2828-1987 Sampling procedures and tables for lot-by-lot inspection by attributes (Apply to inspection of successive lots or batches)

GB 8368-1998 Medical infusion sets for single use (eqv ISO 8536-4-1998)

GB/T 14233.1-1998 Infusion, transfusion, injection equipment for medical use--Part 1: Chemical analysis methods

GB/T 14233.2-1993 Infusion, transfusion, injection equipment for medical use—Part 2: Biological test methods

GB/T 16886.1-2001 Biological evaluation of medical devices--Part 1: Evaluation and testing (idt ISO 10993-1:1997)

YY 0311-1998 General specification for single-use blood flow product

YY 0326.2-2002 Plasmapheresis centrifuge apparatus for single use--Part 2:Plasma tubing

#### **3 General requirements**

##### **3.1 Structure**

The typical separation cup structure is shown in figure 1.



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