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

中华人民共和国医药行业标准

YY 0326.3-2005

**Plasmapheresis centrifuge apparatus for single
use—Part 3: Containers for plasma**
一次性使用离心式血浆分离器
第 3 部分：血浆袋

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Foreword

The general title of YY 0326 is plasmapheresis centrifuge apparatus for single use, including the following parts:

-Part 1: Centrifuge bowl

-Part 2: Plasma tubing

-Part 3: Containers for plasma

Annex A, annex B and annex C of this part are normative annexes.

This part is proposed by technical standardization committee of medical infusion appliances.

This part is under the jurisdiction of Jinan Supervision and Inspection Center for Medical Device Quality of State Food and Drug Administration.

Drafting units of this part: Shandong Medical Instrument Quality Supervision and Shanghai Transfusion Technology Co., Ltd.

Participated drafting units of this standard: Shandong Weigao Group Medical Polymer Co. Ltd. and Shanxi Zhengyuan Science and Technology Development Co., Ltd.

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Part 3: Containers for plasma

1 Scope

This part of YY 0326 specifies the requirements for containers for plasma used with hemostix specified in YY 0328, Plasma tubing specified in YY 0326.2 and plasma centrifuge bowl specified in YY 0326.1. The plasma collected and stored in containers for plasma specified in this part is used to prepare blood products, which cannot be used for clinical blood transfusion.

2 Normative references

The articles contained in the following documents have become this part of YY 0326 when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this part. For the undated documents so quoted, the latest editions shall be applicable to this part.

GB/T 6682 Water for analytical laboratory use - Specification and test methods (GB/T 6682-1992, neq ISO 3696: 1987)

GB/T 14233.2 Test methods for infusion, transfusion, injection equipment for medical use-Part 2: Biological test methods

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

YY 0326.1 Plasmapheresis centrifuge apparatus for single use--Part 1:Centrifuge bowl

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

YY 0328 Single use blood-taking set for blood processing equipment

3 Terms and definitions

The following terms and definitions apply to this part of YY 0326.

3.1

Container for plasma

It refers to bag container designed to be able to connect with the outlet of centrifuge cup specified in YY 0326.1 and used to collect plasma.

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