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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Medical Devices — Disposable membrane plasmaseparator and plasma component separator

次性使用空心纤维血浆分离器和血浆成分分离器

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Foreword

Codeofchina Inc. is in charge of this English translation. In case of any doubt about the English translation, the Chinese original shall be considered authoritative. This standard is drafted in accordance with the rules given in the GB/T 1.1-2009. This standard replaces YY 0465-2009 Disposable Membrane Plasmaseparator. In addition to a number of editorial changes, the following technical deviations have been made with respect to the YY 0465-2003 (the previous edition): — addition of the requirements and test methods for particle shedding from the external cavity (see 5.5 and 6.5); — addition of the requirements and test methods for endotoxin (see 5.10 and 6.10); — addition of the requirements and test methods for separation of hemoglobin content in plasma with plasmaseparator (see 5.11 and 6.11); — addition of the requirements and test methods for filtration rate of plasma components of plasma component separator (see 5.13.3 and 6.13.3); — addition of the requirements and test methods for protein sieving coefficient of plasma component separator (see 5.13.3 and 6.13.3); — addition of the requirements and test methods for validity period (see 5.15 and 6.15); — modification of the test methods for pyrogen (see 6.9; Edition 2009, 6.7.3). Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. The issuing body of this document shall not be held responsible for identifying any or all such patent rights. This standard was proposed by the National Medical Products Administration. This standard is under the jurisdiction of SAC/TC 158 (National Technical Committee 158 on Extracorporeal Circuit Equipments of Standardization Administration of China). The previous editions of this standard are as follows: — YY 0465-2003, YY 0465-2009.

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1 Scope

This standard specifies the terms and definitions, type and model designation, requirements, test method, inspection rules, marking, packaging, transportation and storage of disposable membrane plasmaseparator and plasma component separator. This standard is applicable to disposable membrane plasmaseparator and plasma component separator. The disposable membrane plasmaseparator, hereinafter referred to as plasmaseparator, is used in conjunction with plasmaseparation system to treat various immunological diseases, metabolic disorder and some toxic action and other diseases. The disposable membrane plasma component separator, hereinafter referred to as plasma component separator, is suitable for double filter plasma exchange therapy, which is used in conjunction with plasmaseparator to separate certain relative molecular mass from the separated plasma by membrane separation.

2 Normative References

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The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. GB/T 191 Packaging — Pictorial Marking for Handling of Goods GB/T 1962.2 The Conical Fittings with a 6% (Luer) Taper For Syringes, Needles and Certain Other Medical Equipment — Part 2: Lock Fittings GB/T 13074 Terms of Blood Purification GB/T 14233.1-2008 Test Methods for Infusion, Transfusion, Injection Equipments for Medical Use — Part 1: Chemical Analysis Methods GB/T 16886.1 Biological Evaluation of Medical Devices — Part 1: Evaluation and Testing GB/T 16886.4 Biological Evaluation of Medical Devices — Part 4: Selection of Tests for Interactions with Blood GB/T 16886.5 Biological Evaluation of Medical Devices — Part 5: Tests for In Vitro Cytotoxicity GB/T 16886.10 Biological Evaluation of Medical Devices — Part 10: Tests for Irritation and Delayed-type Hypersensitivity GB/T 16886.11 Biological Evaluation of Medical Devices — Part 11: Tests for Systemic Toxicity

YY/T 0466.1 Medical Devices — Symbols to be Used with Medical Device Labels, Labelling and Information to be Supplied — Part 1: General Requirements

Pharmacopoeia of the People's Republic of China (Edition 2015)

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3 Terms and Definitions

For the purposes of this document, the terms and definitions given in GB/T 13074 and the following apply. process of separating plasma and formed element in blood device consisting of hemodynamic system, monitoring system, capacity balancing system and plasmaseparator, etc. process of separating different relative molecular mass substances in plasma.

4 Type and Model Designation

4.1 Type

4.2 Model designation

Model designation is shown in Figure 1.

5 Requirements

5.1 Appearance

5.5 Particles shedding

The inner/outer cavity of plasmaseparator and plasma component separator shall be clean; the number of particles of 15 μm to 25 μm in 100 mL of eluent shall not be more than 200,

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and that of particles larger than 25 μm shall not be more than 100.

5.6 Chemical properties

5.6.1 Reducing substances (readily oxidizable substance)

The difference between the volume of potassium permanganate solution [c (KMnO4) = 0.002 mol/L] consumed by 20 mL of test fluid and the same batch of blank control fluid shall not exceed 2.0 mL.

5.6.2 Metal ions

5.6.2.

5.6.3 PH value

The difference between the pH values of the test fluid and the same batch of blank control fluid shall not be more than 1.5.

5.6.4 Evaporation residue

5.6.5 UV absorbance

The absorbance of test fluid shall not be larger than 0.1.

5.6.6 Ethylene oxide residual quantity

5.7 Biological safety

The plasmaseparator and plasma component separator shall be subject to biological evaluation according to GB/T 16886.1.

5.8 Sterility

The plasmaseparator and plasma component separator shall be sterile.

5.9 Pyrogen

The plasmaseparator and plasma component separator shall be pyrogen-free.

5.10 Endotoxin

The endotoxin content in plasmaseparator and plasma component separator shall be less than 0.5 EU/mL. 5.

5.12 Sealing property

5.12.1 Tolerable pressure inside the membrane

The blood chamber membrane of plasmaseparator and plasma component separator shall

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