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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1.Structure and Drafting Rules of Standardization Documents"

Drafting.

This document is part 4 of GB 14232 "Bag Plastic Containers for Human Blood and Blood Components". GB 14232 has released the following

part.

---Part 1.Traditional blood bag;

---Part 2.Graphical symbols used for labels and instructions for use;

---Part 3.Blood bag system with special components;

---Part 4.Single blood collection bag system with special components.

This document uses the redrafting law to modify and adopt ISO 3826-4.2015 "Human blood and blood component bag plastic container Part 4

Points. Single blood bag system with special components.

The structure of this document and ISO 3826-4.2015 has been adjusted, and the numbering and sequence of Appendix A and Appendix B have been adjusted.

The technical differences between this document and ISO 3826-4.2015 and the reasons are as follows.

---Regarding normative reference documents, this document has made adjustments with technical differences to adapt to my country's technical conditions and adjustments.

The situation is collectively reflected in Chapter 2 "Normative Reference Documents", and

the specific adjustments are as follows.

* Replace ISO 3696 with GB/T 6682, which is modified to adopt international standards;

* Replace ISO 8536-4 with GB 8368, which is modified to adopt international standards;

* Replace ISO 1135-4 with GB 8369.1 which is modified to adopt international standards;

* Replace ISO 10993-1 with GB/T 16886.1 which is equivalent to the international standard;

* Replace ISO 10993-4 with GB/T 16886.4 which is equivalent to adopting international standards;

* Replace ISO 10993-5 with GB/T 16886.5 which is equivalent to adopting international standards;

* Replace ISO 10993-10 with GB/T 16886.10, which is equivalent to the international standard;

* Replace ISO 10993-11 with GB/T 16886.11 which is equivalent to adopting international standards;

* Replace ISO 10993-12 with GB/T 16886.12, which is equivalent to adopting international standards;

* Deleted ISO 3826-1, ISO 3826-2, ISO 3826-3, ISO 15223-1 and ISO 15747;

* Added reference to the "Pharmacopeia of the People's Republic of China".

The following editorial changes have been made to this document.

---Informative Appendix D Standard Implementation Guide has been added.

Introduction

If required by the national competent authority, the manufacturer or supplier of plastic blood bags shall submit all plastic materials, material components, and materials to the competent authority.

Details of its production method and detailed production information of plastic blood bags, including the chemical name and content of any additives, and what are these additives

What is added by the manufacturer of the plastic blood bag is the details of the raw materials and all the additives that have been used.

GB 14232 provides the performance requirements and test methods of bag-type plastic containers for human blood and blood components. It consists of four parts.

---Part 1.Traditional blood bag. The purpose is to specify the requirements for airtight, sterile plastic blood bags.

---Part 2.Graphical symbols used for labels and instructions for use. The purpose is to give an expression that can be used for blood collection

Graphical symbols for certain information on medical devices and stored medical devices.

---Part 3.Blood bag system with special components. The purpose is to specify a bag-type non-ventilated aseptic plastic container with special components

(Blood bag system) requirements.

---Part 4.Single blood collection bag system with special components. The purpose is to specify the requirements for a single blood collection bag system with special components.

The purpose of the requirements specified in this document is.

a) Ensure that the blood or blood components maintain the required high quality.

b) As far as possible to ensure the safe and effective collection, inspection, storage, separation and infusion of the inner liquid, especially the risks caused by the following reasons

Minimize.

--- Pollution, especially microbial pollution;

---Air plug;

---Identify errors in representative samples of plastic blood bags and contents;

---The interaction between the plastic blood bag and the liquid inside.

c) When used in conjunction with a blood transfusion set specified in GB 8369.1 or other standards, the function is guaranteed to be applicable.

d) In the case of minimum packaging quality and volume, it can provide adequate protection against damage and deterioration.

Bag-type plastic container for human blood and blood components

Part 4.Single blood bag system with special components

1 Scope

This document specifies the requirements (including performance requirements) for a single blood collection bag system with special components. The single blood bag system includes the

One or more special components given.

These special components refer to.

---Acupuncture protection device;