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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 14232.1-2020

Replacing GB 14232.1-2004

Plastics collapsible containers for human blood and blood components - Part 1: Conventional containers

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Foreword

"Bag Plastic Container for Human Blood and Blood Components" consists of the following parts.

---GB 14232.1 Bag-type plastic containers for human blood and blood components Part 1.Traditional blood bags;

---GB/T 14232.2 Bag-type plastic containers for human blood and blood components Part 2.Diagrams for labels and instructions for use

Shape symbol;

---GB 14232.3 Human blood and blood components bag plastic container Part 3.Blood bag system with special components;

This part is Part 1 of "Bag Plastic Containers for Human Blood and Blood Components".

This section was drafted in accordance with the rules given in GB/T 1.1-2009.

This part replaces GB 14232.1-2004 "Human Blood and Blood Components Bag Plastic Container Part 1.Traditional Blood Bag", and

Compared with GB 14232.1-2004, the main technical changes are as follows.

---The standard adoption relationship with ISO 3826-1 was changed from equivalent adoption to modified adoption;

---Modified normative reference documents (see Chapter 2, Chapter 2 of the.2004 edition);

---Modified the definition of plastic blood bag (see 3.1, 3.1 in.2004 edition);

---Modified the plastic blood bag icon (see Figure 1, Figure 1 of the.2004 edition);

---The nominal capacity of the blood bag is increased to 600mL (see Table 1, Table 1 of the.2004 edition);

---Added the requirements for the aseptic connection of the transfer tube (see 5.6.5), and gave the test method (see Appendix B, B.5);

--- Partially revised the lancet requirements and test methods (see 5.7,.2004 edition of 5.7);

---Added the requirements for the position of the blood transfusion socket diaphragm (see 5.8.1, 5.8.1 in the.2004 edition), and added a note (see note 2);

---The blood transfusion socket has increased requirements (see 5.8.3 and 5.8.4);

--- Amendments to Appendix C in conjunction with GB/T 16886 (see Appendix C, Appendix C of the.2004 edition);

--- Amend Appendix NA to Appendix D (see Appendix D, Appendix NA of the.2004 edition).

This part uses the redrafting law to amend and adopt ISO 3826-1.2013 "Human blood and blood component bag plastic container Part 1

Points. Traditional Blood Bag.

The technical differences between this part and ISO 3826-1.2013 and the reasons are as follows.

---Regarding normative reference documents, this section 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 1135-4.2012 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 the international standard;

* Replace ISO 10993-5 with GB/T 16886.5, which is equivalent to the international standard;

* 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 the international standard;

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

* Added GB/T 16886 (all parts) medical device biological evaluation series standards [ISO 10993 (all parts)];

* Added references to GB/T 14232.2 and GB 14232.3;

* Added reference YY/T 0466.1;

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

This section has made the following editorial changes.

---Fixed the misrepresentation in ISO 3826-1.2013, and changed c(MnO4)=0.01 mol/L in A.4.1 to

c(1/5KMnO4)=0.01mol/L;

---Added footnotes to clauses 5.8.1, A.4.2, B.4.2, and C.2.1 to further explain the clauses to facilitate understanding;

---Added informative Appendix D Standard Implementation Guide to avoid disputes in the implementation of the standard.

Please note that certain contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents.

This part is proposed and managed by the State Drug Administration.

The previous releases of the standards replaced by this part are.

---GB 14232-1993, GB 14232.1-2004.

Introduction

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

Details of its production methods 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.

For future standards that contain technological innovations, such as blood bags with leukocyte filters, this section will serve as a basic document.

The purpose of the requirements specified in this section 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 its contents;