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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 8369.1-2019

Transfusion sets for single use -- Part 1: Gravity feed

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Foreword

The full technical content of this standard is mandatory.

GB 8369 "Disposable Blood Transfusion Device" consists of the following parts.

--- Part 1. Gravity blood transfusion;

--- Part 2. Pressure transfusion equipment;

This part is the first part of GB 8369.

This part is drafted in accordance with the rules given in GB/T 1.1-2009.

This part replaces GB 8369-2005 "disposable blood transfusion device", compared with GB 8369-2005, except for editorial modification

The changes are as follows.

--- Standard name added "gravity blood transfusion", the scope is reduced to gravity blood transfusion device (see Chapter 1);

--- Removed the "marking example" of the blood transfusion device (see.2005 version 3.3.1);

--- Revised the Figure 1 blood transfusion legend (see Figure 1, Figure 1 of the.2005 version);

--- Revised the particle contamination indicator and its test method (see A.1,.2005 edition of A.1);

--- Removed the illustration, marking and related requirements of the air intake device, consistent with international standards (see 3.3.2, Figure 2 and.2005)

5.5);

--- Modify the full-text "bottle puncture device" to "transfusion spigot puncturing device", which increases the requirements of the blood transfusion spigot device (see 5.4,

2005 edition of 5.4);

--- Revised the requirements for blood and blood component filters and the corresponding test methods (see 5.6,.2005, 5.7 and A.4);

--- The position requirements of the injection parts are revised to mandatory requirements (see 5.10, 5.11 of the.2005 edition);

--- The outer conical joint requirements are modified to mandatory requirements (see 5.11, 5.12 of the.2005 edition);

--- Revised the requirements for reducing substances and the method of test methods (see 6.1 and B.2, 6.1 and B.2 of the.2005 edition);

--- Biological requirements increase blood component residue assessment and blood component damage assessment (see 7.6 and 7.7);

--- The flag added to the ISO 7000 symbol 2725 indicates the presence of a certain substance of interest (see 8.1

Note);

--- Packaging has increased requirements (see 9.3);

--- Increased disposal requirements (see Chapter 10).

This section uses the redrafting method to modify the use of ISO 1135-4.2015 "medical blood transfusion apparatus part 4. disposable blood transfusion device

Gravity transfusion type.

There are technical differences between this section and ISO 1135-4.2015. The terms involved in these differences have been blanked on the outside of the page.

The vertical single line (-) of the position is marked, and a list of the corresponding technical differences and their causes is given in Appendix E.

This section has made the following editorial changes.

--- Added informative Appendix D, providing guidelines for the design and implementation of infusion sets in China;

--- Added informative Appendix E, giving a list of technical differences and their causes compared to ISO 1135-4.2015.

1 Scope

This part of GB 8369 specifies the material, physical, chemical and biological requirements for disposable, gravity transfusion medical blood transfusion devices.

This section applies to single-use gravity blood transfusion devices for use with blood and blood component containers and intravenous devices.

2 Normative references

The following documents are indispensable for the application of this document. For dated references, only dated versions apply to this article.

Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 1962.2 Syringes, needles and other medical devices 6% (Ruhr) conical joints Part 2. Locking cones

(GB/T 1962.2-2001, ISO 594-2..1998, IDT)

GB/T 6682-2008 Analytical laboratory water specification and test method (ISO 3696.1987, MOD)

GB/T 14232.2 Human blood and blood components - Plastic containers - Part 2. Graphical symbols for labels and instructions

(GB/T 14232.2-2015, ISO 3826-2.2008, IDT)

GB/T 14233.1-2008 Methods of test for infusions, blood trans

GB/T 14233.2 Medical infusion, blood transfusion, and injecting machines - Test methods - Part 2

GB 15811 single-use sterile injection needle (GB 15811-2016, ISO 7864.1993, NEQ)

GB/T 16886.1 Biological evaluation of medical devices - Part 1. Evaluation and testing in the process of risk management

(GB/T 16886.1-2011, ISO 10993-1..2009, IDT)

GB/T 25915.1 Clean room and related controlled environment Part 1. Air cleanliness level (GB/T 25915.1-2010,

ISO 14644-1.1999, IDT)

YY/T 0466.1 Medical devices for the labeling, marking and information of medical devices - Part 1. General requirements

(YY/T 0466.1-2009, ISO 15223-1.2007, IDT)

YY/T 1288 disposable blood transfusion device with nylon blood filter

ISO 3826-1.2013 Human blood and blood components - Plastic containers - Part 1. Traditional blood bags (Plastics

Colapsiblecontainersforhumanbloodandbloodcomponents-Part 1.Conventionalcontainers)

3.1 Name of the blood transfusion device

The name of the blood transfusion device component is shown in Figure 1.

3.2 Sterile maintenance

The blood transfusion device should have a protective cover to keep the inside of the blood transfusion container sterile before use.