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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 8369.2-2020

Transfusion sets for single use - Part 2: With pressure infusion apparatus use

Issued on: November 17, 2020 **Implemented on: June 1, 2022**

Issued by: State Administration for Market Regulation, China National Standardization Administration

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Foreword

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

---Part 1.Gravity blood transfusion;

---Part 2.Pressure blood transfusion equipment;

This part is Part 2 of GB 8369.

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

This part uses the redrafting law to amend and adopt ISO 1135-5.2015 ``Medical blood transfusion equipment Part 5.Pressure blood transfusion equipment

The second use of blood transfusion.

Compared with ISO 1135-5.2015, there are technical differences in this part. The clauses involved in these differences have been

The vertical single line (?) of the position is marked, and a list of the corresponding technical differences and their reasons is given in Appendix F.

This section also made the following editorial changes.

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---Modify the standard name to "Disposable Blood Transfusion Set Part 2.Pressure Blood Transfusion Equipment";

---Informative Appendix E has been added, providing guidelines for the design and implementation of blood transfusion sets in my country;

---Informative Appendix F has been added, which gives a list of the corresponding technical differences and their reasons compared with ISO 1135-5.2015.

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.

Single use blood transfusion set

Part 2.Pressure blood transfusion equipment

1 Scope

This part of GB 8369 specifies the use of single-use blood transfusion devices for blood transfusion equipment that can produce pressures of.200 kPa (2 bar) and below.

Material, physical, chemical and biological requirements.

This section applies to blood transfusion sets used for pressure transfusion equipment that are used in conjunction with blood and blood component containers and intravenous injection equipment.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this document.

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

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

GB 8369.1 One-time use blood transfusion set Part 1.Gravity blood transfusion (GB 8369.1-2019, ISO 1135-4.2015, MOD)

GB 14232.1-2020 Bag-type plastic containers for human blood and blood components Part 1.Traditional blood bags (ISO 3826-1.2013, MOD)

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

GB/T 14233.1-2008 Medical infusion, blood transfusion, injection equipment inspection

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methods Part 1.Chemical analysis methods

GB/T 14233.2 Medical infusion, blood transfusion, and injection equipment inspection methods Part 2.Biological test methods

GB/T 16886.1 Biological Evaluation of Medical Devices Part 1.Evaluation and Testing in the Process of Risk Management

GB/T 25915.1 Clean room and related controlled environment Part 1.Air cleanliness grade

YY/T 0466.1 Medical devices are used for medical device labeling, marking and information symbols. Part 1.General requirements

YY/T 1288 Nylon blood filter for disposable blood transfusion apparatus

ISO 80369-7.2016 Small aperture connectors for medical liquids and gases-Part 7.Connectors for intravascular or subcutaneous applications

3 Terms and definitions

The following terms and definitions apply to this document.

Note. These terms and definitions are exclusively used in Appendix D.

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