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GB/T 19335-2022

Blood flow products for single use — General specification

一次性血液循环产品 — 一般规格

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1 Scope

This document specifies the general specifications of blood flow products for single use. This document applies to single-use blood flows and their integrated accessory lines, including products consists of liquid lines and pressure monitoring lines, etc. (hereinafter referred to as “blood flow”).

2 Normative references

The contents of the following documents constitute essential provisions of this document through the normative references in the text. Among them, only the version corresponding to the date applies to this document for references dated, and its latest version (including all modification orders) applies to this document for references not dated. GB 8369 (all parts) Transfusion sets for single use GB/T 14233.1-2008 Test methods for infusion, transfusion, injection equipments for medical use - Part 1: Chemical analysis methods GB/T 14233.2 Test methods for infusion, transfusion, injection equipment for medical use - Part 2: Biological test methods GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process GB/T 19633.1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems YY/T 0316 Medical devices - Application of risk management to medical devices YY 0581.1 Infusion access adapters - Part 1: Needle access adapters (Heparin plugs) YY 0581.2 Infusion access adapter - Part 2: Needleless access adapters YY/T 0615.1 Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices YY/T 0923 Needleless access ports for fluid lines and blood lines - Test method for microbial ingress YY/T 1288-2015 - Nylon blood filter nets for transfusion equipments for single use YY/T 1556 Test methods for particle contamination of infusion, transfusion and injection equipments for medical use ISO 18250-8:2018 Medical devices—Connectors for reservoir delivery systems for healthcare applications— Part 8: Citrate-based anticoagulant solution for apheresis applications ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications —Part 7: Connectors for intravascular or hypodermic applications

3 Terms and definitions

There are no terms and definitions to be defined in this document.

4 General requirements

Established risk assessment procedures shall be used to design blood flow products. When blood flow products are transported, stored, installed, used normally and maintained in

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accordance with the manufacturer's instructions, no risks that are not reduced to an acceptable level and are relevant to its intended application shall be identified under normal and single-failure conditions, using risk management procedures in accordance with YY/T 0316.

The manufacturer shall give special consideration to additional risk control measures since they may not be able to follow all the requirements identified in this document.

See Appendix A for the design and evaluation requirements for blood flow products.

5 Materials

The lines directly or indirectly in contact with blood shall be manufactured by choosing materials that meet the relevant standards. Lysates from the blood flow due to chemical or physical action by anticoagulants and/or maintenance solution, blood and blood components shall be within the specified limits.

6 Design

6.1 Protective cap

Each inlet and outlet of the blood flow (except for the inlet and outlet of the pressure monitoring connector / transducer protector) shall be provided with a protective cap that is secure and easy to remove.

6.2 Injection parts

6.2.1 Needleless injection parts

Needleless injection parts on the blood flow shall meet the relevant requirements of YY 0581.2. Manufacturers are advised to evaluate the microbial ingress of the needleless access ports in accordance with YY/T 0923.

6.2.2 Needle injection parts

The puncture site of the needle injection parts on the blood flow shall comply with relevant requirements of YY 0581.1.

6.3 Connectors

6.3.1 Luer connectors

Luer connectors shall conform to the requirements of ISO 80369-7.

6.3.2 Reservoir connectors

Connectors to the citrate anticoagulant shall conform to the requirements of ISO

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