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NATIONAL STANDARD OF THE

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Extracorporeal systems for blood purification — Extracorporeal blood/fluid circuits for haemodialysers, haemodiafilters, haemofilters and haemoconcentrators

血液净化体外循环系统

血液透析器、血液透析滤过器、血液滤过器及血液浓缩器用体外循环血路/液路

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4.1 Biological Evaluation

Components in the extracorporeal blood/fluid circuit that come into direct or indirect contact with blood shall be evaluated for biological hazard.

4.2 Sterility

Components in the extracorporeal blood/fluid circuit that come into direct or indirect contact with blood must be sterile.

Note: Sterility instructions (specific instructions for sterility of the product or non-intact package sterile products) as well as instructions for sterilization methods, are provided on the primary packaging.

4.3 Bacterial Endotoxins

The bacterial endotoxin content of components in direct or indirect contact with extracorporeal blood/fluid circuit should not exceed 20 EU/set.

4.4 Mechanical Characteristics

4.4.1 Structural Integrity

The extracorporeal blood/fluid circuit should be able to withstand a pressure of 1.5 times the manufacturer’s recommended maximum positive pressure and 1.5 times the manufacturer’s recommended maximum negative pressure.

4.4.2 Connectors to Hemodialyzers, Hemodiafilters, Hemofilters, or Hemoconcentrators

4.4.2.1 Unless the connection is designed as an integrated system, the design dimensions of connectors to hemodialyzers, hemodiafilters, hemofilters, or hemoconcentrators are shown in Figure 1 and Table 1. Connectors made of rigid materials must meet the dimensional requirements of Figure 1 and Table 1.

4.4.2.2 There should be no leakage between the connectors and the matching device.

β ——— angle of thread; γ ——— dimension taper rate;

δ ——— thread (double thread pitch);

4.4.3 Connectors to Vascular Access Devices

Except where the extracorporeal circulation circuit and the vascular access device are an integrate system, the connectors made of rigid materials for connecting to vascular access devices should be 6% Luer-lock connectors and meet the performance requirements of YY/T 0916.7 (ISO 80369-7:2016□ 0916.7 (ISO 80369-7:2021, IDT) .

4.4.4 Connectors to ancillary components

All parts of the extracorporeal blood/fluid circuits intended to be connected to non-integral aucillary components, such as heparin lines, pressure-transducer lines, medication-administration lines and level adjustment lines, shall be equipped with connectors that meet the performance requirements of YY/T 0916.7.

4.4.5 Color coding

The patient-connection end and connectors to hemodialyzers, hemodiafilters, hemofilters, or hemoconcentrators of the arterial side should be marked red, and the venous side should be marked blue. The colour coding shall be prominently displayed within 100 mm of the end of the tubing.

Note: The arterial side is defined as the segment of the extracorporeal circuit taking the blood from the patient. The venous side is defined as the extracorporeal circuit component that returns the blood to the patient.

Different colours shall be used to identify other parts of the system in accordance with to the output of the manufacturer’s risk management process.

4.4.6.1 Needle access ports

Needle access ports shall not leak. The access ports shall be designed so as to minimize the risk of needle piercing the tube completely and causing injury to the user.

4.4.6.2 Needleless access ports

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4.8 Expiration Date

Products within the expiration date must meet specified requirements.

Note: The expiration date is indicated on the product packaging.

5.1 Overview

This chapter provides type test methods corresponding to various performance characteristics. Other test methods with proven feasibility and reliability may also be used. Type testing is conducted at therapeutically relevant temperatures.

5.2 Biological Evaluation

The biological performance of components in the extracorporeal blood circuit/fluid circuit that are in direct or indirect contact with blood should be evaluated in accordance with the provisions of GB/T 16886.1.

5.3 Sterility

Components in the extracorporeal blood circuit/fluid circuit that come into direct or indirect contact with blood shall be tested according to the methods specified in the Pharmacopoeia of the People's Republic of China.

5.4 Bacterial Endotoxins

5.5 Mechanical Properties

5.5.1 Structural Integrity

5.5.1.1 Positive Pressure Test

Testing may be performed using one of the following methods.

of 1.5 times the manufacturer's recommended maximum pressure. Maintain pressure for a minimum of 10 min and inspect the device for leakage.

5.5.1.2 Negative Pressure Test

Compliance shall be determined by either of the following tests.

mmHg) below atmospheric pressure. Maintain pressure for a minimum of 10 min and inspect the device for visual signs of leakage.

manufacturer's recommended maximum negative pressure or 93,3 kPa (700 mmHg) below atmospheric pressure. Maintain pressure for a minimum of 10 min and inspect the device for any air bubble leaks.

5.5.2 Connectors for connecting haemodialyzers, haemodiafilters, haemofilters, and haemoconcentrators

5.5.2.1 The dimensions of rigid connectors shall be verified using universal or special gauges. The matching gauges and connector dimensions are shown in Figure 2 to 5 and