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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 12260-2017

Replacing GB 12260-2005

Cardiopulmonary bypass systems - Roller blood pump

心肺转流系统 滚压式血泵

Issued on: December 29, 2017 **Implemented on: July 1, 2019**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine;
Standardization Administration of the PRC

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Foreword

The technical content of this standard is mandatory. This standard was drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces GB 12260-2005 "artificial heart-lung machine rolling blood pump." The main differences between this standard and GB 12260-2005 are as follows:

--- Modify the definition of constant current operation and pulsating operation (see 4.3,.2005 version 4.3);

--- Modify the maximum constant flow requirements, only the main pump requirements (see 5.3.2,.2005 version 5.3.2);

--- Modify the maximum pulsatile flow requirements, only the main pump requirements (see 5.4.4,.2005 version 5.4.4);

--- Increased safety monitoring requirements (see 5.7). Please note that some of this document may be patentable. The issuing agencies of this document do not bear the responsibility of identifying these patents. This standard is proposed and managed by the State Food and Drug Administration. This standard is drafted by the State Food and Drug Administration Guangzhou Medical Device Quality Supervision and Inspection Center. The main drafters of this standard. Tu Rong, Fan Xiang, once pretty, Wang Peilian. This standard replaces the standards previously issued as follows:

--- GB 12260-1990, GB 12260-2005. Cardiopulmonary bypass system rolling blood pump

1 Scope

China's mandatory standard for the roller blood pump of a cardiopulmonary bypass system - the pump that takes over the work of the heart while it is stopped for surgery. Rollers compress a length of tubing against a curved raceway and push the blood along it, which has the great virtue that the blood touches nothing but the inside of the tube, and the great danger that the flow is a direct function of the roller speed: the pump will deliver whatever it is set to deliver, against any resistance, whether or not there is blood to deliver. The whole

technical content of the standard is mandatory. It specifies the terms and definitions, the types, composition and basic parameters, the requirements, the test methods, and the marking, packaging, transport and storage of the roller blood pump. The requirements cover the flow, both in constant and in pulsatile operation, with the maximum flow now specified for the main pump alone, the accuracy and stability of delivery, the occlusion setting of the rollers, which decides between haemolysis if too tight and backflow if too loose, the speed control and its display, the behaviour on loss of mains with the hand crank that must let the perfusionist keep the circulation going, and the safety monitoring introduced in this edition - the detection of the conditions that must stop the pump before they reach the patient. The electrical safety follows GB 9706.1, the environmental requirements GB/T 14710, the symbols YY/T 0466.1 and the vocabulary YY/T 1145. Issued on 29 December 2017 and in force since 1 July 2019, it replaces GB 12260-2005.

This standard specifies the cardiopulmonary bypass system rolling blood pump terms and definitions, type, composition, basic parameters, requirements, test methods, standard Log, packaging, transportation and storage. This standard applies to cardiopulmonary bypass system roller blood pump (hereinafter referred to as blood pump), the product for medical units for surgery and rescue, temporary Cardiopulmonary bypass for cardiac function or local perfusion.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version applies to this article Pieces. For undated references, the latest edition (including all amendments) applies to this document.

GB/T 191 Packaging - Pictorial signs (GB/T 191-2008, ISO 780..1997, MOD)

GB 9706.1 medical electrical equipment Part 1. General requirements for safety (GB 9706.1-2007, IEC 60601-1. 1988, IDT)

GB 9706.15 Medical electrical equipment - Part 1-1. General safety requirements Collateral standards. Medical electrical system safety requirements (GB 9706.15-2008,

IEC 60601-1-1..2000, IDT) Environmental requirements and test methods for medical electrical appliances GB/T 14710-2009

YY/T 0466.1 Medical Devices Labeling, Labeling and Information Symbols for Use in Medical Devices - Part 1. General Requirements (YY/T 0466.1-2016, ISO 15223-1..2012, IDT)

YY/T 1145 cardiopulmonary bypass system terminology

3 Terms and definitions

YY/T 1145 defined terms and definitions apply to this document. 4 type, composition and

basic parameters

4.1 type Constant current rolling, rolling pulsating.

4.2 composition Rolling blood pump by the blood pump (such as single head pump or double head pump), monitoring system, the base includes the bracket (if any).

4.3 Basic parameters

4.3.1 constant current operation.

a) The maximum flow of the main pump should not be less than 6000mL/min;

b) The minimum speed should not exceed 1r/min.

4.3.2 pulsating operation.

a) beat frequency should meet the manufacturer's requirements;