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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY 1412-2016

Cardiopulmonary bypass systems - Centrifugal pump

心肺转流系统 离心泵

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Foreword

The technical content of this standard is mandatory. This standard is drafted in accordance with the rules given in GB/T 1.1-2009. Please note that some of the contents of this document may involve patents. The issuer of this document does not assume responsibility for the identification of these patents. This standard is proposed by the State Food and Drug Administration. This standard is defined by the National Standard Committee on Medical Extracorporeal Circulation Equipment (SAC/TC158) and is responsible for the interpretation. The drafting unit, the State Food and Drug Administration Guangzhou Medical Device Quality Supervision and Inspection Center, Maikewei (Shanghai) Medical Equipment Limited. The main drafters of this standard, Li Shi, Wang Ping, Fan Xiang, Li Aijun, Gu Xiaowei. Cardiopulmonary bypass system centrifugal pump

1 Scope

YY 1412 is the mandatory Chinese standard for the centrifugal pumps used in cardiopulmonary bypass and ECMO, the pump heads that move a patient's entire circulation while the heart is stopped or supported. It sets the requirements such a pump has to meet and the test methods that verify them, covering the flow it delivers against pressure, the haemolysis it causes as blood passes through it, the seal and bearing integrity over hours or days of continuous running, the coupling to the drive and the behaviour if drive is lost. Centrifugal pumps replaced roller pumps for long runs precisely because they damage blood less, so haemolysis is the measurement that justifies the design. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the terminology and definition, classification, composition, parameters, requirements, test methods, signs, and use of CPR centrifugal pumps. Brochures, packaging, transportation, storage. This standard applies to cardiopulmonary bypass system centrifugal pump (hereinafter referred to as centrifugal pump). The centrifugal pump for medical units for surgery and rescue, For cardiopulmonary bypass and extracorporeal membrane oxygenation surgery in the blood perfusion or local perfusion, can be used independently and/or supporting the use of artificial heart-lung machine. This

standard does not apply.

--- Roller pump; - extracorporeal circulation;

--- gas filter; Attract the pump

--- centrifugal pump head.

2 Normative reference documents

The following documents are indispensable for the application of this document. For dated references, only the dated edition applies to this article Pieces. For undated references, the latest edition (including all modifications) applies to this document.

GB/T 191 packaging and storage icon Medical electrical equipment - Part 1. General requirements for safety

GB 9706.1 General rules for the use of industrial products

GB/T 9969 Environmental requirements and test methods for medical appliances GB/T 14710-2009

YY/T 0466.1 Symbols for medical devices for labeling, labeling and providing information on medical devices - Part 1. General requirements

YY/T 1145 Artificial heart - lung machine terminology

3 Terms and definitions

YY/T 1145 and the following terms and definitions apply to this document.

3.1 Centrifugal pump pump head centrifugal pump-head Centrifugal centrifugal force centrifugal force of the disposable perfusion device. 4 classification, composition, parameters

4.1 Classification

4.1.1 according to the different ways of blood flow are divided into. centrifugal constant flow, centrifugal pulsating.

4.1.2 According to the maximum speed is divided into.