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

# YY 1048-2016

Replacing YY 1048-2007

## Cardiopulmonary bypass systems - Extracorporeal blood circuit

心肺转流系统 体外循环管道

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## Foreword

This standard is drafted in accordance with the rules given in GB/T 1.1-2009. This standard replaces YY 1048-2007 "artificial heart and lung cardiopulmonary bypass pipeline", this standard and YY 1048-2007 main technology The differences are as follows: - increased requirements for validity (see 4.5) and corresponding test methods (see 5.5); - modified biological performance requirements (see 4.3.1,.2007 edition 4.3.1); - modified no leak test conditions (see 5.2.1,.2007 edition 5.2.1); - Modification of the test solution preparation method (see 5.4.1,.2007 edition 5.4.1);

--- Delete size requirements (2007 edition 3.4);

--- Remove inspection rules (2007 edition 6). 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 by the National Medical Extracorporeal Circulation Equipment Standardization Technical Committee (SAC/TC158) centralized. The drafting of this standard. Ningbo Feilal Medical Supplies Co., Ltd., the State Food and Drug Administration Guangzhou Medical Equipment Quality Supervision Supervisory center. The main drafters of this standard. Hong Liang Tong, Xu Zhaosheng, Xiong Wei, He Xiaofan, Shen Junbo. This standard replaced the previous version of the standard release.

--- WS2-301-1983;

--- GB 12264-1990;

--- YY 91048-1999;

--- YY 1048-2007. Cardiopulmonary bypass system for extracorporeal circulation

## 1 Scope

YY 1048 is the mandatory Chinese standard for the extracorporeal blood circuit used in cardiopulmonary bypass, the tubing set that carries a patient's entire circulation to the oxygenator and back during open heart surgery. It sets the requirements such a circuit has

to meet and the test methods that verify them, covering the biocompatibility of the blood-contacting surfaces, the mechanical strength and kink resistance of the tubing, the integrity of every connection, the resistance to spallation where a roller pump works the tube, and the sterility of the assembly. A disconnection or a burst line during bypass exsanguinates the patient in seconds. It replaces YY 1048-2007. Being a YY standard without the /T suffix, compliance is compulsory in China.

This standard specifies the cardiopulmonary bypass system of extracorporeal circulation pipeline (hereinafter referred to as the pipeline) classification and naming, requirements, test methods, signs, packages Equipment, transportation, storage. This standard applies to cardiopulmonary bypass system used in the extracorporeal circulation of the pipeline and its associated with the auxiliary pipeline, the product in the cardiovascular Surgery for extracorporeal circulation as a blood channel and channel connection used for one-time use.



## 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

GB/T 1962.1 Syringes, injection needles and other medical devices 6% (Ruhr) Conical joints Part 1. General requirements

GB/T 1962.2 Syringes, injection needles and other medical devices 6% (Ruhr) Conical joints Part 2. Locking joints Standard Test Method for Drinking Water of Metals - Metals Indicators

GB/T 5750.6-2006 General rules for the use of industrial products GB/T 9969

GB/T 14233.1-2008 Methods of test for medical infusion, transfusion, and injectable utensils - Part 1. Chemical analysis methods

GB/T 14233.2-2005 Methods of examination for medical infusion, transfusion, and injectable utensils - Part 2. Biological test methods

GB/T 16886.1 Biological evaluation of medical devices - Part 1. Evaluation and testing in risk management

GB 18279 Sterilization and routine control of ethylene oxide for medical devices

GB 18280 Health care products Sterilization confirmation and routine control requirements Radiation sterilization General technical conditions for disposable blood use products

GB 19335-2003 Packaging, marking, transportation and storage of medical polymer

products

YY/T 0313-1998 Medical devices - Symbols for labeling, marking and providing information on medical devices - Part 1. Generic Claim Test methods for packaging of sterile medical devices - Part 1. Guidelines for accelerated aging testing

YY/T 0681.1-2009 Classification and composition

3.1 pipeline generally by the pipeline, joints, pump and other components.