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

YY/T 1271-2016

**Cardiopulmonary bypass systems-Suction catheter for single
use
(English Translation)**

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Foreword

All technical contents of this standard are mandatory:

This standard is drafted in accordance with the rules given in GB/T 1.1-2009:

Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying these patents:

This standard was proposed by China Food and Drug Administration:

This standard is under the jurisdiction of the National Standardization Technical Committee of Medical Extracorporeal Circulation Equipment (SAC/TC158):

1 Scope

This standard specifies the classification, structure, requirements, test methods, signs, and labels of sterile single-use suction tubes (hereinafter referred to as suction tubes):

label, instruction manual, packaging, transportation and storage:

This standard is applicable to suction tubes for cardiopulmonary bypass systems, suction tubes for left heart exhaust, suction decompression or Reduce the load on the left heart and attract fluids such as blood in the cardiac surgery field:

2 Normative references

The following documents are indispensable for the application of this document: For dated references, only the dated version applies to this document pieces: For undated references, the latest version (including all amendments) applies to this document:

GB/T 191-2008 Packaging, storage and transportation icon marks GB/T 9969-2008 General Rules for Instructions for Use of Industrial Products GB/T 14233.1-2008 Test methods for medical infusion, blood transfusion and injection equipment Part 1: Chemical analysis methods GB/T 14233.2-2005 Test methods for medical infusion, blood transfusion and injection equipment Part 2: Biological test methods GB/T 16886.1 Biological evaluation

of medical devices Part 1: Evaluation and testing in the risk management process GB 18279 Medical Device Ethylene Oxide Sterilization Confirmation and Routine Control GB 18280 Sterilization Confirmation and Routine Control Requirements for Healthcare Products Radiation Sterilization GB 19335-2003 General technical requirements for disposable blood products YY/T 0149-2006 Test method for corrosion resistance of stainless steel medical devices YY/T 0466.1-2009 Symbols for medical device labeling, marking and providing information for medical devices Part 1: General Require YY/T 0681.1-2009 Test Methods for Sterile Medical Device Packaging Part 1: Guidelines for Accelerated Aging Tests

3 Classification and structure

3.1

Classification

This standard stipulates that according to the use of the product, it is divided into two types: left heart drainage tube and cardiac suction tube (right heart suction tube); left heart drainage tube is mainly used for body in extracorporeal circulation heart surgery, it is used to exhaust the left heart, decompress or reduce the left heart load, and the heart cavity suction tube is mainly used in heart surgery with extracorporeal circulation:

It is used to attract fluids such as blood in the cardiac surgery field, and transfer them back to the blood reservoir:

The suction tube should be specified by the outer diameter or outer circumference of the product: Recommended in millimeters (mm), if not in millimeters (mm) place, the instruction manual should have a comparison table: The specific specifications, models and sizes are stipulated by the manufacturer according to its actual situation:

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