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

YY/T 1273-2016

**Roller pump for auxiliary blood purification
(English Translation)**

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Table of Contents

Foreword
1 Scope
2 Normative references
3 Terms and Definitions
4 Requirements

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 terms, definitions, requirements, test methods, marks, and usage of roller pumps for auxiliary blood purification (hereinafter referred to as roller pumps):

Instructions and packaging, transportation and storage:

This standard applies to the blood purification auxiliary roller pump defined in 3:1: The rolling pump cannot be used independently for blood purification treatment:

This standard does not apply to:

- Hemoperfusion equipment;
- blood cell separation equipment;
- Continuous blood purification equipment;
- Immunoabsorption equipment;
- hemodialysis device;
- Hemodiafiltration device;

---Centrifugal pump;

---Artificial heart-lung machine rolling blood pump:

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 Packaging, storage and transportation icon marks GB 9706.1 Medical Electrical Equipment Part 1: General Safety Requirements GB/T 9969 General Rules for Instructions for Use of Industrial Products GB/T 13074 Terminology for blood purification GB/T 14710-2009 Environmental requirements and test methods for medical electrical appliances YY/T 0466.1 Symbols for Medical Device Labeling, Marking and Information Provision for Medical Devices Part 1: General Requirements

3 Terms and Definitions

The following terms and definitions defined in GB/T 13074 apply to this document:

A power device that uses rolling to assist blood extracorporeal circulation during blood purification treatment:

4 Requirements

4.1

Normal working conditions the manufacturer's specification or the following conditions shall be met:

a) The ambient temperature is 5°C~40°C;

YY 1273-2016