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

YY/T 1856-2023

**General requirements for the safety of blood, intravenous fluid
and irrigation fluid warmers**

血液、静脉药液、灌洗液加温器安全通用要求

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Foreword

This document is in accordance with the provisions of GB/T 1:1-2020 "Guidelines for Standardization Work Part 1: Structure and Drafting Rules for Standardization Documents" drafting: Please note that some contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by the State Drug Administration: This document is under the jurisdiction of the National Standardization Technical Committee of Medical Infusion Sets (SAC/TC106): This document was drafted by: Shandong Institute of Medical Devices and Drug Packaging Inspection, Beijing Jingjing Medical Equipment Co., Ltd., Baxter Medical Supplies Trading (Shanghai) Co., Ltd., Smith Medical Devices (Beijing) Co., Ltd: The main drafters of this document: Yu Xiaohui, Zhao Zenglin, Zhang Ke, Liu Guichi, Zhu Qingliang, Liu Yinghui, Mou Pengtao, Liu Jun, Li Yan:

Due to the frequent use of warmers for blood, IV fluids, and irrigation fluids on patients in the operating room, intensive care unit, and other settings, there is a need for Special attention is given to fluid warmers: The purpose of this document is to establish safety requirements for fluid warmers that minimize the risk to patients and operators, and to specify that compliance has been Confirmed test: K (Kelvin) is a recognized unit symbol for absolute temperature and temperature difference, but since all measurements are made with the Celsius scale equipment, so °C is used throughout this document: The "*" marked in front of the item number in this document indicates that there is further explanation of the item in Appendix A: Warmers for blood, venous medicine, and lavage fluid General Safety Requirements

1 Scope

YY/T 1856 sets the general safety requirements for the warmers used on blood, intravenous fluids and irrigation fluids. Warming exists to prevent the hypothermia that follows rapid transfusion or large-volume irrigation, but the same energy that solves that problem can haemolyse red cells or burn a patient if the control fails. The document specifies what such a warmer has to achieve and the test methods that verify it: the temperature actually delivered at the patient end, the accuracy and stability of the control,

the protection against overheating, the alarms and the behaviour under fault conditions. It applies across the different fluid types rather than to one product, which makes it the umbrella document a specific warmer standard builds on. For a manufacturer, this is the text a Chinese registration is assessed against.

This document specifies the general safety requirements for fluid warmers (collectively referred to as fluid warmers) (see 3:2) for blood, intravenous drug solutions, and lavage fluids: This document applies to warmers for blood, IV fluids, and irrigation fluids: This document does not apply to:

- Fluid warmers for non-pipelines, such as warming cabinets, fresh frozen plasma/fresh red blood cell thawing devices, electric cooker heaters;
- Extracorporeal/cardiac bypass warming circulatory system;
- Warmer integrated into the dialysis unit:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB/T 1002 Types, basic parameters and dimensions of single-phase plugs and sockets for household and similar purposes

GB 9706.1-2020 Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance

GB/T 17465 (all parts) Household and similar appliance couplers

3 Terms and Definitions

The following terms and definitions defined in GB 9706.1-2020 apply to this document: 3:

1 Fluid path fluidpath A channel intended to infuse or lavage a patient from its source (such as a blood bag, infusion bag, or irrigation fluid bag) to the patient: NOTE: The fluid pathway is an applied part: 3:2 fluid warmer fluidwarmer fluid expected to flow in a line (through a closed path) from a source (such as a blood bag, infusion bag, or irrigation fluid bag) to the patient Heated equipment: include:

- warmer for blood in the pipeline;
- Warmer for in-line intravenous infusion;
- A warmer for the lavage fluid in the pipeline: *3:3 set temperature setpointtemperature

The temperature set by the operator on the fluid warmer at the desired temperature of blood, IV solution, or irrigation fluid: 3:

4 Temperature from the fluid warmer sensor and displayed by the fluid warmer:

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