ICS 11.040.25
CCS C30

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1842.7-2023

Medical devices - Connectors for reservoir delivery systems for healthcare applications - Part 7: Connectors for intravascular infusion

医疗器械 医用贮液容器输送系统用连接件 第7部分：血管内输液用连接件

Issued on: January 13, 2023 **Implemented on: January 15, 2024**

Issued by: National Medical Products Administration

Table of Contents

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. This document is Part 7 of YY/T 1842 "Connectors for Delivery System of Medical Liquid Storage Containers for Medical Devices". YY/T 1842 has The following parts have been published.

1.General requirements and general test methods;

6.Neural applications;

7.Connections for intravascular infusion;

8.Apheresis citrate anticoagulant application. This document identically adopts ISO 18250-7.2018 "Connectors for Medical Devices and Medical Liquid Storage Container Delivery Systems - Part

7.Blood vessels Connecting parts for internal infusion". 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 Provincial Institute of Medical Devices and Drug Packaging Inspection, Zhejiang Fuerte Medical Devices Co., Ltd., Shandong Dongwei Gao Group Medical Polymer Products Co., Ltd., Anhui Tiankang Medical Technology Co., Ltd., Beijing Guoyi Huaguang Certification Co., Ltd. company. The main drafters of this document. Li Yuanyu, Su Weidong, Cong Rinan, Zhou Yuyan, Wang Meiying, Liu Yang, Zhang Luwen, Bai Baodong.

When formulating the YY 0916 (ISO 80369) "Small-aperture Connectors for Medical Liquids and Gases" series of standards, it was found that the wrongly connected wind The risks are not limited to the connections to the patient, but also the connections used for the reservoir portion at the end of the system have a potentially high risk of misconnection. For a number of reasons, these reservoir connections do not fit within the scope of the ISO 80369 series of standards, so it was decided to Connector connectors are specially developed as an

independent standard series. The ISO 18250 series of standards takes into account the misalignment of reservoir connections in different applications. Risk of misconnection, including standardized IV piercers specified in ISO 8536-4 and ISO 1135-4. During the formulation of YY/T 0916.3, it was found that various medical device standards stipulated a variety of intravenous infusion puncture devices, but no There are requirements defining the geometry and material of the female port of an IV reservoir container. However, various standards define the performance of the female port. YY/T 1842 "Connectors for Delivery System of Medical Liquid Storage Containers for Medical Devices" is proposed to be composed of the following parts.

1.General requirements and general test methods;

3.Gastrointestinal application;

6.Neural applications;

7.Connections for intravascular infusion;

8.Apheresis citrate anticoagulant application. This document specifies the design, dimensions and materials of female ports. This document refers to existing performance standards. This document contains the Test to prove that the piercer and the female port are not connected to other connectors of YY/T 1842 series liquid storage containers. This document also includes the requirements for allowing the traditional YY/T 0916.7 Luer connectors to be used as liquid reservoir connectors for intravascular applications full analysis. This document only specifies the interface requirements for the connectors of intravascular infusion storage containers and intravascular infusion sets. This document is not a product standard. If there is an asterisk (*) before the beginning of the title, paragraph or table title, relevant instructions and guidelines are given in Appendix A. For medical equipment, medical liquid storage container, delivery system Connectors - Part

1 Scope

YY/T 1842.7 specifies the connectors used for intravascular infusion in reservoir delivery systems. Small-bore connector standards exist for one reason: to make it physically impossible to connect a line to the wrong route. Misconnections that put enteral feed into a vein, or an intravenous drug into an epidural catheter, have killed patients, and the international response was to give each application a geometry that will not mate with the others. This part covers the intravascular application, setting the dimensions, the mechanical performance and the test methods that verify both fit and non-interconnectability. For a manufacturer of infusion sets, pumps or reservoir systems, this is the document that determines whether a connector may be sold for intravascular use in China, and it is checked at registration.

This document specifies the dimensions, as well as the design and function performance requirements. This document does not specify dimensional or performance requirements

for medical devices or accessories using these connectors. These requirements in dedicated medical device or given in the attached standard. Example

1.The medical devices that can use the connector of the intravascular infusion storage container are as follows:

---The infusion port of the intravenous infusion storage container and the piercer of the matched intravenous infusion/intravascular infusion set/pipe, such as. intravenous infusion bag/container and intravenous infusion The piercer inlet end of the intravenous infusion set;

--- Devices intended to be used in series between the infusion port of the intravenous infusion storage container and the piercer of the associated intravenous infusion/supply line;

---Syringes and IV sets using Luer connectors. The following connections are outside the scope of this document.

---Corps specified in ISO 8536-2;

--- The mixing/adding port of the intravenous infusion storage container and the intended matching device. Example

2.Rubber stoppers for injection into reservoir containers and associated drug addition devices (syringes, needles, reconstitution devices, and other devices for accessing mixing or addition ports auxiliary equipment).

--- Injection ports of non-electrically driven (ie elastic) pumps. Note

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 8369.1-2019 Disposable blood transfusion sets Part