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

YY/T 1842.6-2022

**Medical devices - Connectors for reservoir delivery systems for
healthcare applications - Part 6: Neural applications**

医疗器械 医用贮液容器输送系统用连接件 第6部分：神经应用

(English Translation)

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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 of Standardization Documents" drafted.

This document is part 6 of YY/T 1842 "Connectors for Medical Devices and Medical Fluid Storage Container Delivery Systems". YY/T 1842 has the following sections have been published.

- Part 1: General requirements and general test methods;
- Part 6: Neurological applications;
- Part 7: Connectors for intravascular infusion;
- Part 8: Application of apheresis citrate anticoagulant.

This document is equivalent to ISO 18250-6:2019 "Connectors for medical device medical fluid storage container delivery systems - Part 6: Neurological application".

A chapter "Terms and Definitions" has been added to this document.

Please note that some content of this document may be patented. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

During the development of the ISO 80369 series of standards "Small Bore Connectors for Medical Liquids and Gases" it was found that the risk of incorrect connections is not limited to the connections to the patient, the connections for the reservoir portion at the end of the system also have a potentially high risk of wrong connections. for many reasons Since these reservoir connections are not suitable for the scope of application of the ISO 80369

series, it was decided to specially develop these reservoir connections.

Issue a separate standard series. The 18250 series takes into account the risk of incorrect connection of reservoir connections in different applications, including in Standardized venous infusion sets specified in ISO 8536-4 and ISO 1135-4.

Note: Even if there is no requirement in the current special standards related to medical devices, manufacturers are encouraged to apply the connectors specified in this document to medical devices. expect repair when ordering a special medical device standard, the dimensional requirements for connectors specified in this document will be included.

YY/T 1842 "Connectors for Medical Liquid Storage Container Delivery Systems for Medical Devices" is intended to consist of the following parts.

- Part 1: General requirements and general test methods;
- Part 3: Gastrointestinal application;
- Part 6: Neurological applications;
- Part 7: Connectors for intravascular infusion;
- Part 8: Application of apheresis citrate anticoagulant.

Connectors for the delivery system of medical liquid storage containers for medical devices
Part 6: Neural Applications

1 Scope

This document specifies requirements for recommended connectors for use on the outlet end of a neurological application reservoir and on the inlet end of a neurological delivery device.

2 Normative references

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, dated citations documents, only the version corresponding to that date applies to this document; for undated references, the latest edition (including all amendments) applies to this document.

ISO 18250-1 Connectors for medical device medical fluid storage container delivery systems - Part 1: General requirements and general test methods Note. YY/T 1842.1-2022 Connectors for medical device medical liquid storage container delivery systems - Part 1: General requirements and general test methods (ISO 18250-1:2018, IDT) ISO 80369-6 Small bore connectors for medical liquids and gases - Part 6: Connectors for shaft applications (Small bore tions) Note. YY/T 0916.6-2022 Small bore connectors for medical liquids and gases Part 6: Connectors for shaft applications (ISO 80369-6:2016, IDT)

3 Terms and Definitions

Terms and definitions defined in ISO 18250-1 and ISO 80369-6 apply to this document.

4 Neural application reservoir outlet connector

4.1

The outlet end of the nerve application reservoir shall be a male axon locking connection (N2) in accordance with ISO 80369-6.

4.2

The connector should not be removed from the liquid container by the user.

5 Inlet connector of nerve drug delivery device

5.1

The inlet end of the nerve delivery device shall be a female axonal locking connection (N2) in accordance with ISO 80369-6.

5.2

The connector should not be removed from the drug delivery device by the user.

Note: See Appendix A for relevant instructions, and Appendix B for the record of the analysis results of incorrect connections.