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

YY/T 1148-2024

Replacing YY/T 1148-2009

Spinal needles

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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. This document replaces YY/T 1148-2009 "Lumbar Puncture Needle". Compared with YY/T 1148-2009, except for structural adjustments and editorial changes, In addition to the above, the main technical changes are as follows:

- a) The scope has been changed (see Chapter 1, Chapter 1 of the.2009 edition);
- b) Added material requirements (see Chapter 4);
- c) Added appearance requirements (see 5.1);
- d) Added integrity requirements (see 5.3);
- e) Added scale line requirements (see 5.7);
- f) Sterilization requirements have been added (see Chapter 6). Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Syringes (Needles) (SAC/TC95). This document was drafted by: Shanghai Institute of Medical Device Inspection, Shanghai Ess Medical Technology Co., Ltd., Zhejiang Kangdelai Medical Devices Medical Devices Co., Ltd., Zhejiang Fulte Medical Devices Co., Ltd., and Xinjiang Uygur Autonomous Region Drug Inspection Institute. The main drafters of this document are. Sun Rui, Hua Songhe, Wang Dan, Sun Hongrong, Liu Mian, Zhang Qian, Su Weidong, Zhu Yizhong and Zhang Shuwen. The previous versions of this document and the documents it replaces are as follows:

---First published in 1977 as YY/T 1148-1977, first revised in.2009;

---This is the second revision. Lumbar puncture needle

1 Scope

YY/T 1148 is the product standard for the spinal needle used for lumbar puncture and spinal anaesthesia. It is a simple device whose details matter disproportionately: the tip geometry determines whether the needle splits the dura or cuts it, which is what decides the rate of post-puncture headache, and the stylet fit, the flow through a very fine bore and the visibility of cerebrospinal fluid return govern whether the procedure succeeds on the first attempt. The standard sets the dimensional, mechanical and performance requirements and the test methods behind them. The 2024 edition takes effect on 20 July 2025. For a manufacturer or an importer of spinal needles for the Chinese market, this is the governing product standard.

This document specifies the nominal outer diameter of 0.40mm~1.60mm for use in human subarachnoid block (abbreviated as lumbar anesthesia). Requirements for lumbar puncture needles (abbreviated as lumbar puncture needles) used for puncture and injection of medicinal solutions. This document applies to reusable lumbar puncture needles. This document does not apply to single-use lumbar puncture needles for anesthesia.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 191 Pictorial markings for packaging, storage and transportation

GB/T 18457 Stainless steel needle tubes for medical device manufacturing YS/T

76 Lead Brass Drawing Rod

YY/T 0916.6 Small-bore connectors for medical liquids and gases Part

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4 Structure and classification

4.1 Structural type The structure and component names of the lumbar puncture needle are shown in Figure 1.