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

YY/T 2004.1-2026

**Traditional Chinese Medicine Instruments - Dermal Needling -
Part 1: Tapping Technique**

中医器械 皮肤针 第1部分：叩刺式

(English Translation)

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 1 of YY/T 2004 "Traditional Chinese Medicine Instruments - Dermal Needles". YY/T 2004 has already published the following parts.

--Part 1: Tapping Technique.

This document is modified to adopt ISO 23958-1:2022 "Traditional Chinese Medicine - Single-use Dermal Needles - Part 1: Percussion Method".

This document has undergone the following structural adjustments compared to ISO 23958-1:2022.

--4.2 corresponds to 4.2.1 in ISO 23958-1:2022, and 6.1 corresponds to 4.2.2 in ISO 23958-1:2022, and 6.2 corresponds to...

Sections 6.1 and 6.3 of ISO 23958-1:2022 correspond to sections 6.2 and 6.4 of ISO 23958-1:2022.

In ISO 23958-1:2022, 6.3 and 6.5 correspond to 6.4 and 6.6, respectively. In ISO 23958-1:2022, 6.5 and 6.7 correspond to...

6.6 of ISO 23958-1:2022.

The technical differences between this document and ISO 23958-1:2022, and the reasons

therefor, are as follows.

--The following terms have been removed from the scope. "disposable tapping needles," "skin-penetrating needles," and "not suitable for rolling needles." the content regarding "reusable tapping needles or skin needles with detachable tapping tips" is adapted to the actual situation in my country.

--Merge the terms and definitions of skin needles with those of tapping skin needles, and add a description of the structure to the definition of tapping skin needles.

The description (see 3.1) is more accurate;

--The terms and definitions of rolling skin needle, primary packaging, and intermediate packaging have been removed and do not need to be defined in this document;

--Added classification based on whether it is sterile (see 4.3) to adapt to the actual situation in my country;

--ISO 10993-1 (see 5.1) has been replaced with the normatively referenced GB/T 16886.1 to adapt to my country's technical conditions and improve reliability.

Operability;

--The number of taps has been increased in the test method for needle tip firmness (see 6.3) to improve operability and objectivity;

--The test method for the firmness between the puncture head and the needle handle has been improved by increasing the suspension time of the test weight (see 6.4) to enhance operability and...

objectivity;

--ISO 6507-1 (see 6.5) has been replaced with the normatively referenced GB/T 4340.1 to adapt to my country's technical conditions and improve operability.

Actual nature;

--Added a test method for corrosion resistance (see 6.6) to improve operability;

--YY/T 0149-2006 has been added as a reference (see 6.6);

--ISO 10993-7 (see 6.7) has been replaced with the normatively referenced GB/T 16886.7 to adapt to my country's technical conditions and improve reliability.

Operability;

-- ISO 15223-1 (see 7.1.3.1, 7.2.2.1) has been replaced by the normatively referenced YY/T 0466.1 to adapt to my country's technical requirements.

Conditions to improve operability;

--The requirements for labeling in the primary packaging have been changed (see 7.1.3.1), and the requirements for sterile skin needle labeling are now a separate item (see 7.1.3.2).

To adapt to my country's actual situation;

--The labeling requirements for intermediate packaging have been changed (see 7.2.2), adding requirements for labeling of non-sterile skin needles [see...].

7.2.2.1k)], the requirements for sterile skin needle labels are listed separately (see 7.2.2.2) to adapt to the actual situation in my country;

--YY/T 0802.1 has been added as a reference (see 7.2.2.1);

--Transportation and storage have been removed to adapt to my country's actual situation.

The following editorial changes have been made to this document.

--To align with existing standards, the standard name has been changed to "Traditional Chinese Medicine Instruments. Dermal Needles - Part 1: Percussion Technique";

--ISO 15510 has been replaced by GB/T 4240 (see 5.2) for informational reference; GB 18278.1 has replaced ISO 17665-1 and GB 18278.1.

18279 replaced ISO 11135, and GB 18280.1 replaced ISO 11137-1 (see 6.7).

--Example of a modified skin needle specification (see 4.1);

--The top view of the five needles of the dispersed tapping head has been deleted from Figure 1;

--The needle body material has been changed from X5CrNi18-9 listed in ISO 15510 to 06Cr19Ni10 as specified in GB/T 4240.

X7CrNi18-9 (see 5.2).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the Standardization Technical Unit for Traditional Chinese Medicine Instruments (SMD/TU 008).

Introduction

Dermal needles are a traditional Chinese medicine instrument that acts on the skin, acupoints, or meridians through tapping or rolling techniques. They are categorized into tapping and rolling methods.

There are two types. YY/T 2004 "Traditional Chinese Medicine Instruments - Dermal Needles" aims to provide the requirements and test methods for dermal needles used in

traditional Chinese medicine, and is proposed to be divided into two parts.

Composition.

--Part 1: Percussion. The purpose is to provide the basic requirements and experimental methods for percussion dermal needles.

--Part 2: Rolling Type. The purpose is to provide the basic requirements and test methods for rolling skin needles.

Traditional Chinese Medicine Instruments. Dermal Needles - Part 1: Tapping Technique

1 Scope

This document specifies the specifications, structure and classification, materials, performance requirements, packaging and labeling of tapping dermal needles (hereinafter referred to as "dermal needles").

This document applies to tapping-type skin needles.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

document.

GB/T 4340.1 Metallic materials - Vickers hardness test - Part 1: Test methods (GB/T 4340.1-2024, ISO 6507-1.

2023, MOD)

GB/T 16886.1 Biological evaluation of medical devices - Part 1: Evaluation and testing in the risk management process (GB/T 16886.1-2022, ISO 10993-1:2018, IDT) GB/T 16886.7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residue (GB/T 16886.7-2015) ISO 10993-7:2008 (IDT) YY/T 0149-2006 Test method for corrosion resistance of stainless steel medical devices (ISO 13402:1995, MOD) YY/T 0466.1 Symbols for medical devices used to provide information to manufacturers - Part 1: General requirements (YY/T 0466.1-2023, ISO 15223-1:2021, MOD) YY/T 0802.1 Handling of Medical Devices - Information provided by Medical Device Manufacturers - Part 1: Medical Devices of Medium to High Risk (YY/T 0802.1-2024, ISO 17664-1:2021, MOD)