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**Traditional Chinese medicine —  
Dermal needles for single use —**

**Part 1:  
Tapping-type**

*Médecine traditionnelle chinoise — Aiguilles dermiques à usage  
unique —*

*Partie 1: Type marteau*

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see [www.iso.org/directives](http://www.iso.org/directives)).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see [www.iso.org/patents](http://www.iso.org/patents)).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 249, *Traditional Chinese medicine*.

A list of all parts in the ISO 23958 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at [www.iso.org/members.html](http://www.iso.org/members.html).

## Introduction

A dermal needle is a traditional Chinese medicine device for stimulating acupuncture points, meridians or skin by tapping or rolling. It is composed of a group of needles which stimulate a wide area of skin effectively. The stimulating strength of dermal needles depends on the density of the needles, the sharpness of the needle tips and the length of the needle body, among other things.

Dermal needles are widely used in East and Southeast Asia, the Americas, Europe and Oceania.

According to different operation modes, dermal needles for single use may be divided into two types: tapping-type and roller-type.

This document deals with tapping-type dermal needles for single use, while ISO 23958-2 deals with roller-type dermal needles.

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# Traditional Chinese medicine — Dermal needles for single use —

## Part 1: Tapping-type

### 1 Scope

This document specifies the particular requirements for the basic safety and essential performance of tapping-type dermal needles for single use. It applies to tapping-type dermal needles that have the capacity to penetrate the skin.

It specifies structure and dimension, materials, and performance requirements for appearance and cleanliness, corrosion resistance, sterility, packaging and identification, transit and storage of tapping-type dermal needles.

It does not apply to roller-type dermal needles, reusable tapping-type dermal needles or devices incorporating a detachable tapping head.

### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 6507-1, *Metallic materials — Vickers hardness test — Part 1: Test method*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

### 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

#### 3.1

##### **dermal needle**

device composed of several short needles used for stimulating the meridian or skin

#### 3.2

##### **tapping-type dermal needle**

dermal needle with a tapping head

Note 1 to entry: The tapping head is used to tap the skin.

Note 2 to entry: Plum-blossom needles and seven-star needles are typical tapping-type dermal needles.

**3.3  
roller-type dermal needle**

dermal needle composed of a handle and a roller, which has evenly spaced micro needles

**3.4  
needle body**

part of the needle from the tip to the tapping head

Note 1 to entry: See [Figure 1](#).

**3.5  
needle tip**

sharp apex at the end of the dermal needle body intended to penetrate the skin

[SOURCE: ISO 17218: 2014, 3.3, modified]

**3.6  
handle**

part that connects to the tapping head and can be held and used for tapping by the operator

Note 1 to entry: See [Figure 1](#).

**3.7  
tapping head**

multi-cluster needle installed at the head of the tapping-type dermal needle for skin tapping

Note 1 to entry: The tapping head has one or two sides where needles are placed. These two types are referred to as single-headed and double-headed tapping-type dermal needles.

**3.8  
outer circle**

circle connecting the outermost needles installed on the tapping head

**3.9  
extensive stimulation head**

side of the tapping head where needles are evenly spaced along concentric circles

Note 1 to entry: See [Figure 1](#).

**3.10  
intensive stimulation head**

side of the tapping head with a cluster of short needles

Note 1 to entry: This type of needle cluster is located at the opposite side of the tapping head to the extensive stimulation head.

Note 2 to entry: See [Figure 1](#).

**3.11  
primary package**

sealed or closed packaging system that forms a microbial barrier, directly enclosing the tapping-type dermal needle

[SOURCE: ISO 17218:2014, 3.9, modified — definition revised and Note 1 to entry removed.]

**3.12  
secondary package**

package containing one or more primary packages for distribution and storage

[SOURCE: ISO 17218:2014, 3.10]



## 4 Structure and dimensions of tapping-type dermal needles

### 4.1 Size designation

The size of the needle body shall be designated by:

- the nominal diameter of the needle body (or the maximum diameter of the needle tip), expressed in millimetres;
- the nominal length of the needle body, expressed in millimetres.

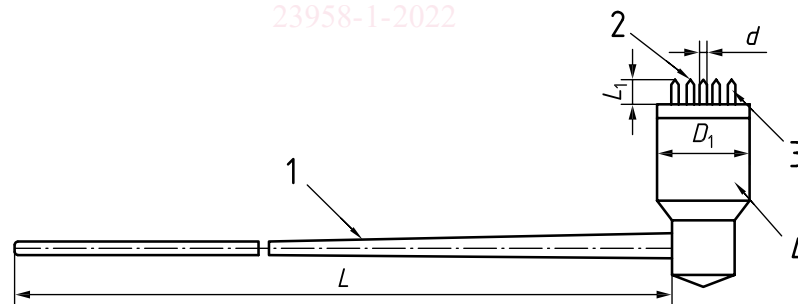
The size shall be referred to as “the designated metric size” and specified as a) × b).

EXAMPLE      $\varnothing 0,16 \text{ mm} \times 1,0 \text{ mm}$ .

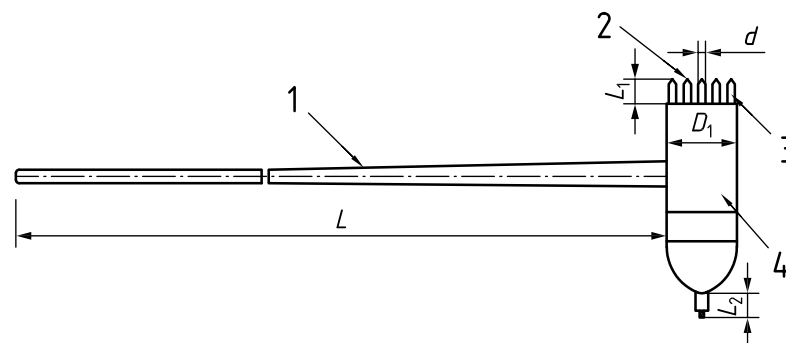
### 4.2 Structure and dimensions of tapping-type dermal needle

#### 4.2.1 Structure of tapping-type dermal needle

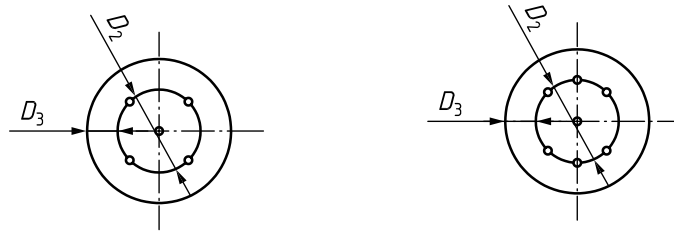
- A tapping-type dermal needle consists of three parts: a needle body, a tapping head and a handle.
- The tapping-type dermal needle can be divided into a single-headed needle and a double-headed needle based on whether it has an intensive stimulation head.
- In single-headed tapping-type dermal needles, one side of the tapping head is formed with evenly arranged needles along concentric circles.
- In double-headed tapping-type dermal needles, one side of the tapping head is formed with evenly spaced needles along concentric circles and the other side is formed with a certain number of short needles clustered.
- A typical structure of a tapping-type dermal needle is shown in [Figure 1](#).



a) Single-headed tapping-type dermal needle



b) Double-headed tapping-type dermal needle



c) Typical structures of an extensive stimulation head (top view)

**Key**

- 1 handle
- 2 needle tip
- 3 needle body
- 4 tapping head
- $L$  length of the handle
- $L_1$  length of the needles on the extensive stimulation head
- $L_2$  length of the needles on the intensive stimulation head
- $d$  diameter of the needle body
- $D_1$  diameter of the tapping head
- $D_2$  diameter of the extensive stimulation head
- $D_3$  distance of the outer circle from the margin of the extensive stimulation head

**Figure 1 — Typical structure of a tapping-type dermal needle**

**4.2.2 Dimensions of tapping-type dermal needle**

The nominal diameter of the needle body and the length of the needle body and handle should be measured using a gauge as specified in [Table 1](#).

**Table 1 — Nominal dimensions of tapping-type dermal needle**

Part	Nominal dimensions mm	Tolerance
Length of the handle ( $L$ )	$120 \leq L \leq 250$	$\pm 5,0$
Length of the needles on the extensive stimulation head ( $L_1$ )	$3,0 \leq L_1 \leq 5,0$	$\pm 0,50$
Length of the needles on the intensive stimulation head ( $L_2$ )	$3,0 \leq L_2 \leq 4,0$	$\pm 0,50$
Diameter of the needle body ( $d$ )	$0,35 \leq d \leq 0,80$	$\pm 0,02$
Diameter of the tapping head ( $D_1$ )	$8 \leq D_1 \leq 15$	$\pm 0,50$
Diameter of the extensive stimulation head ( $D_2$ )	$6 \leq D_2 \leq 13$	$\pm 0,50$
Distance of the outer circle from the margin of extensive stimulation head ( $D_3$ )	$D_3 < 10$	$\pm 0,50$

**5 Materials**

**5.1 General**

The biocompatibility of the needle body shall be assessed and documented according to the guidance and principles given in ISO 10993-1.

Conformity is demonstrated by one of the following:

- a) analogy with published data;