



**Sterile acupuncture needles  
for single use**

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  - Complementary Healthcare Council
  - Consumers Federation of Australia
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Australian Standard<sup>®</sup>

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## PREFACE

This Standard was prepared by the Standards Australia Committee HE-031, Traditional Chinese Medicine.

The objective of this Standard is to ensure the product safety and efficacy for the sterile acupuncture needle for single use. To achieve this qualitative and quantitative evaluation methods are provided to evaluate sharpness and puncture performance of the needle tip, an important aspect of clinical significance. In addition, the Standard specifies terms and definitions, nominal needle body diameter and length dimension tolerance, needle body drawing strength, needle body hardness, resistance to needle body breakage and a test method for resistance to corrosion for the needle body.

This Standard is identical with, and has been reproduced from ISO 17218:2014, *Sterile acupuncture needles for single use*.

As this Standard is reproduced from an International Standard, the following applies:

- (a) In the source text 'this International Standard' should read 'this Australian Standard'.
- (b) A full point substitutes for a comma when referring to a decimal mark.

None of the normative references in the source document have been adopted as Australian or Australian/New Zealand Standards.

The term 'informative' has been used in this Standard to define the application of the annex to which it applies. An 'informative' annex is only for information and guidance.

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## INTRODUCTION

This International Standard applies to sterile acupuncture needles for single use (specialized for filiform needles) used by professional acupuncturists for acupuncture treatment. Sterile acupuncture needles for single use are sterilized by the manufacturer, and the healthcare professional can open the sealed package and use the needle immediately.

In order to encourage innovation, this International Standard does not enforce the combination of the needle diameter and length. However, considering the clinical usage requirements, the standard provides the specifications for the needle diameter and length.

The sharpness and puncture performance of the needle tip are of very important clinical significance. [Annex A](#) states the guidelines and the evaluation methods for the intensity and the sharpness of the needle tip, while [Annex B](#) provides two qualitative and quantitative evaluation methods to determine the puncture performance of the needle tip.

The qualitative methods to evaluate the puncture performance of needle tip are described in [Annex B](#). The methods are simple, direct and practical. It makes them especially suitable for routine inspection and for cross-comparison of the acupuncture needles' clinical application. They also play a very important role in the enhancement of the quality of the needle tip. The methods to evaluate the puncture performance of the needle tip can be used to further evaluate the puncture and puncture performance of the acupuncture needle. Currently, the more appropriate method is to use the needle tip to pierce through polyurethane material; however, this method has not yet been implemented internationally.

Considering the consistency of standards in the future, this standard provides the methods to evaluate the puncture performance of the needle tip and ranks [5.3.1.2](#) as recommended. The standard does not provide the sharpness index of the piercing through polyurethane material by the needle tip. This index will be added to the standard when it becomes appropriate. To improve product quality, all inspection reports should include the inspection information as well as the results of the performance evaluation.

Since every manufacturer's design, production and sterilization methods are different, no regulations exist for the materials of the acupuncture needle handle. Still, the needle body and the needle handle of acupuncture needle should have good biocompatibility.

In order to ensure product safety and efficacy, the manufacturer should perform risk analysis and enforce risk management in addition to adhering to the requirements of local rules and regulations, the relevant background data of the medical devices and clinical practice throughout the entire duration of the product's life cycle. ISO 14959 has provided manufacturers a framework for the effective management of hazards associated with the use of medical devices.

In some countries, the requirements proposed here are subject to legal sanctions. Such rules and regulations should take precedence over the standards set forth in this document.

## AUSTRALIAN STANDARD

**Sterile acupuncture needles for single use****1 Scope**

This International Standard specifies the requirements for the sterile acupuncture needles for single use (specialized for filiform needles).

**2 Normative references**

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 6507-1:2005, *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 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

**3 Terms and definitions**

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

**3.1****body of the needle**

part of the acupuncture needle that is inserted into the human body

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

**3.2****handle of the needle**

part of the acupuncture needle that is not inserted into the human body

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

**3.3****tip of the needle**

sharp apex at the end of the acupuncture needle body that is inserted into the human body

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

**3.4****root of the needle**

part of the acupuncture needle that connects the needle body to the needle handle

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

**3.5****tail of the needle**

end part of the needle handle at the opposite side of the tip of the needle

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