

Australian Standard™

**Sterile hypodermic needles
for single use**



This Australian Standard was prepared by Committee HE-009, Hypodermic Equipment—General Medical. It was approved on behalf of the Council of Standards Australia on 26 July 2002 and published on 27 September 2002.

The following are represented on Committee HE-009:

Auckland Healthcare, New Zealand
Australian Chamber of Commerce and Industry
Australian College of Operating Room Nurses
Australian Medical Association
Certification Bodies (Australia)
Commonwealth Department of Health and Ageing
Federation of Sterilizing Research and Advisory Councils of Australia
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Australian Standard™

Sterile hypodermic needles for single use

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PREFACE

This Standard was prepared by the Australian members of Joint Standards Australia/Standards New Zealand Committee HE-009, Hypodermic Equipment—General Medical, to supersede AS 1946—1984, *Hypodermic equipment—Single-use needles (sterile) for general medical use*. After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

This Standard has been reproduced from, and is identical to, ISO 7864:1993, *Sterile hypodermic needles for single use*.

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

- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (b) In the source text ‘this International Standard’ should read ‘this Australian Standard’.
- (c) A full point should be substituted for a comma when referring to a decimal marker.

The terms ‘normative’ and ‘informative’ have been used to define the application of the annex to which they apply. A ‘normative’ annex is an integral part of a Standard, whereas an ‘informative’ annex is only for information and guidance.

References to International Standards should be replaced by references to the following Australian or Australian/New Zealand Standards:

<i>Reference to International Standard</i>		<i>Australian/New Zealand Standard</i>	
ISO		AS	
594	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment	1600	Medical equipment—Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment
594-1	Part 1: General requirements	1600.1	Part 1: General requirements
594-2	Part 2: Lock fitting	—	
3696	Water for analytical laboratory use—Specification and test methods	—	
6009	Hypodermic needles for single use—Colour coding for identification	—	
7886	Sterile hypodermic syringes for single use	1094	Medical equipment—Single-use syringes (sterile) for general medical use
7886-1	Part 1: Syringes for manual use		
		AS/NZS	
8601	Data elements and interchange formats—Information interchange—Representation of dates and times	3802	Data elements and interchange formats—Information interchange—Representation of dates and times
		AS	
9626	Stainless steel needle tubing for the manufacture of medical devices	2145	Stainless steel needle tubing for manufacture of medical devices

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NOTES

AUSTRALIAN STANDARD

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

This International Standard specifies requirements for sterile hypodermic needles for single use of nominal outside diameters 0,3 mm and 1,2 mm.

It does not apply to dental needles.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2:1991, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 6009:1992, *Hypodermic needles for single use — Colour coding for identification.*

ISO 7886-1:—¹⁾, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use.*

1) To be published.

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*

3 Nomenclature

The nomenclature for components of hypodermic needles for single use is shown in figure 1 together with the designation for length l ; nomenclature for needle points is shown in figure 2.

4 Cleanliness

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the hypodermic needle tube shall appear free from particles and extraneous matter.

When examined under $\times 2,5$ magnification, the hub socket shall appear free from particles and extraneous matter.

5 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with annex A shall be within one unit of pH of that of the control fluid.

6 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption