AS 2145—2002
ISO 9626:1991

Australian Standard™

Stainless steel needle tubing for manufacture of medical devices

Standards Australia

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.

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Australian Chamber of Commerce and Industry

Australian College of Operating Room Nurses

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Certification Bodies (Australia)

Commonwealth Department of Health and Ageing

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Australian Standard™

Stainless steel needle tubing for manufacture of medical devices

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PREFACE

This Standard was prepared by the Australian members of the Joint Standards Australia/Standards New Zealand Committee HE-009, Hypodermic Equipment—General Medical, to supersede AS 2145—1985, *Hypodermic equipment—Hypodermic needle tubing*. 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 9626:1991, *Stainless steel tubing for manufacture of medical devices.*

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 term 'normative' has been used in this Standard to define the application of the annex to which it applies. A 'normative' annex is an integral part of a Standard.

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

Reference to International Standard		*Australian Standard*	
ISO		AS	
683	Heat-treatable steels, alloy steels and free-cutting steels	1444	Wrought alloy steels—Standard, hardenability (H) series and hardened and tempered to designated mechanical properties
683-13	Part 13: Wrought stainless steels		
3696	Water for analytical laboratory use—Specification and test methods	—	

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NOTES

AUSTRALIAN STANDARD

Stainless steel needle tubing for manufacture of medical devices

1 Scope

This International Standard specifies the dimensions, surface and mechanical properties of normal- and thin-walled tubing of designated metric sizes 3,4 mm to 0,3 mm, and of extra-thin-walled tubing of designated metric sizes 2,1 mm to 0,6 mm.

Because no data are available, this International Standard does not specify stiffness properties for extra-thin-walled tubing of designated metric sizes 0,8 mm; 0,9 mm; 1,2 mm; 1,4 mm; 1,8 mm and 2,1 mm.

This International Standard applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this International Standard. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in this International Standard.

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 683-13:1986, *Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*

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

3 Materials

Tubing shall be made from austenitic stainless steel of types 10, 11, 16, 20, 21 or 23 in accordance with ISO 683-13.

4 Surface finish

When examined by normal or corrected vision, the outside surface of the tubing shall be smooth and free from defects.

5 Cleanliness

When examined by normal or corrected vision, the surfaces of the tubing shall be free from metal soil and processing agents.

6 Limits for acidity and alkalinity

When tested in accordance with annex A, an extract of the tubing prepared in accordance with annex B shall, when corrected for the volume of titrant required for the control fluid, require not more than 0,04 ml of sodium hydroxide solution or not more than 0,12 ml of hydrochloric acid solution to reach the end-point of the titration.

7 Size designation

Tubing shall be designated by the nominal outside diameter expressed in millimetres (i.e. the designated metric size) and by its category, i.e. normal-walled, thin-walled, or extra-thin-walled.