

Australian Standard[®]

Infusion sets for single use, gravity feed



This Australian Standard® was prepared by Committee HE-021, Transfusion equipment. It was approved on behalf of the Council of Standards Australia on 23 June 2006. This Standard was published on 4 October 2006.

The following are represented on Committee HE-021:

- Australian Chamber of Commerce
 - Australian College of Operating Room Nurses
 - Australian Red Cross
 - College of Emergency Nursing Australasia
 - Commonwealth Department of Health and Ageing
 - The Medical Industry Association of Australia
-

This Standard was issued in draft form for comment as DR 06113.

Standards Australia wishes to acknowledge the participation of the expert individuals that contributed to the development of this Standard through their representation on the Committee and through public comment period.

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Infusion sets for single use, gravity feed

Originated as part of AS 2385—1980.
Previous edition part of AS 2385—1990.
Revised in part and redesignated as AS 8536—2006.

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Published by Standards Australia, GPO Box 476, Sydney, NSW 2001, Australia

ISBN 0 7337 7691 4

PREFACE

This Standard was prepared by the Standards Australia Committee HE-021, Transfusion equipment, to supersede, in part, AS 2385—1990, *Single-use (sterile) infusion sets for general medical use*.

This Standard is identical with, and has been reproduced from ISO 8536-4:2004, *Infusion equipment for medical use—Part 4: Infusion sets for single use, gravity feed*.

The objective of this Standard is to specify requirements for single use gravity feed infusion sets for medical use in order to ensure their compatibility with containers for infusion solutions and intravenous equipment and to provide guidance on specifications relating to the quality and performance of materials used in infusion sets and to present designations for infusion set components.

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.

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

- (a) Its number appears on the cover and title page while the international standard number appears only on the cover.
- (b) In the source text ‘this part of ISO 8536’ should read ‘this Australian Standard’.
- (c) A full point substitutes for a comma when referring to a decimal marker.

References to International Standards should be replaced by references to Australian or Australian/New Zealand Standards, as follows:

<i>Reference to International Standard</i>		<i>Australian 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 fittings	1600.2	Part 2: Lock fittings
7864	Sterile hypodermic needles for single use	1946	Sterile hypodermic needles for single use

Only international references that have been adopted as Australian Standards have been listed.

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NOTES

AUSTRALIAN STANDARD

Infusion sets for single use, gravity feed

1 Scope

This part of ISO 8536 specifies requirements for single-use, gravity feed infusion sets for medical use in order to ensure their compatibility with containers for infusion solutions and intravenous equipment.

Secondary aims of this part of ISO 8536 are to provide guidance on specifications relating to the quality and performance of materials used in infusion sets and to present designations for infusion set components.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this part of ISO 8536.

2 Normative references

The following referenced documents are indispensable for the application 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 594-1:1986, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*

ISO 594-2:1998, *Conical fittings with 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 7864:1993, *Sterile hypodermic needles for single use*

ISO 14644-1:1999, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness*

ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*

3 General requirements

3.1 The nomenclature to be used for components of infusion sets and of a separate air-inlet device is given in Figures 1, 2 and 3. These figures illustrate examples of the configuration of infusion sets and air-inlet devices; other configurations may be used provided they lead to the same results. Infusion sets as illustrated in Figure 2 should only be used for collapsible plastics containers. Infusion sets as illustrated in Figure 2 used with separate air-inlet devices as illustrated in Figure 3, or infusion sets as illustrated in Figure 1, shall be used for rigid containers.