AS 1094.1—2004
ISO 7886-1:1993
(Incorporating Amendment No. 1)

Australian Standard™

Sterile hypodermic syringes for single use

Part 1: Syringes for manual 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 17 November 2003.

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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 syringes for single use

Part 1: Syringes for manual 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, in part, AS 1094—1993, *Medical equipment — Single-use syringes (sterile) for general medical use.*

This Standard incorporates Amendment No. 1 (October 2005). The changes required by the Amendment are indicated in the text by a marginal bar and amendment number against the clause, note, table, figure or part thereof affected.

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 with, ISO 7886-1:1993, *Sterile hypodermic syringes for single use,* Part 1*: Syringes for manual use,* and Technical Corrigendum 1:1995. The corrigendum has been incorporated in the ISO text.

The materials of the syringe should not only be compatible with injection fluids but should be such that the risk of triggering serious allergic reaction is minimized.

Additional information has been included in Appendix ZA in order to provide guidelines for syringes with detachable needles to prevent accidental needle stick injuries or reuse of the syringe-needle combination (or both) after injection.

The objective of this revision is to adopt ISO 7886-1:1993, including its Technical Corrigendum, to fit in with the new regulatory requirements of the Therapeutic Goods Administration.

This Standard does not specify a range of syringe sizes and allows the syringes to be marked with graduations at greater than the nominal capacity.

A1 This Standard permits the use on package labelling of the ISO symbol for ‘Do not re-use’, but continues to require the written word. Manufacturers are encouraged to use the symbol so as to increase familiarity with it among purchasers and users.

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

(a) Its number does not appear on each page of the text, and its identity is shown only on the cover and title page.

(b) In the source text, ‘this part of ISO 7886’ 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 in this Standard to define the application of the annex or appendix to which they apply. A ‘normative’ annex or appendix is an integral part of a Standard, whereas an ‘informative’ one is for information or guidance only.

The references to international Standards should be replaced by references to the following Australian or Joint Australian/New Zealand Standards:

Reference to International Standard or other publication		*Australian/New Zealand Standard*	
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

ISO		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

Any international Standards not listed do not have an Australian/New Zealand equivalent.

CONTENTS

Annexes

INTRODUCTION

This part of ISO 7886 does not give requirements or test methods for freedom from biological hazard. Guidance on biological tests relevant to hypodermic syringes is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such an evaluation should include the effects of the process whereby the syringes are sterilized. However, national regulations may exist in some countries, and these will override the guidance in ISO 10993-1.

Materials to be used for the construction of syringes are not specified as their selection will depend to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. Guidance on some aspects of the selection of materials is given in annex E.

The materials of the syringe should be compatible with injection fluids. If this is not the case, the attention of the user should be drawn to the exception by labelling the primary container. It is not practicable to specify a universally acceptable test method for incompatibility. However, recommended methods are given in annex F. These test methods can be regarded only as a means of indicating compatibility. The only conclusive test is that of an individual injection fluid with a specific syringe.

Manufacturers of pharmaceuticals use solvents in injectable preparations. Such solvents should be tested by the manufacturer of the injectable preparation for any possible incompatibility with the materials frequently used in syringe construction. The types of material that have received wide acceptance are included in annex E. If an incompatibility exists, the injection should be suitably labelled. The impossibility of testing any one injection fluid with all available syringes is recognized and it is strongly recommended that regulatory authorities and relevant trade associations should recognize the problem and take appropriate measures to assist manufacturers.

Hypodermic syringes specified in this part of ISO 7886 are intended for use with hypodermic needles specified in ISO 7864.

This part of ISO 7886 does not cover syringes for the injection of insulin (see ISO 8537).

In some countries, national pharmacopoeia or government regulations are legally binding and their requirements may take precedence over this part of ISO 7886.

AUSTRALIAN STANDARD

Sterile hypodermic syringes for single use
Part 1:
Syringes for manual use

1 Scope

This part of ISO 7886 specifies requirements for sterile single-use hypodermic syringes made of plastics materials and intended for the aspiration of fluids or for the injection of fluids immediately after filling.

It excludes syringes for use with insulin (see ISO 8537), single-use syringes made of glass, syringes with needles permanently attached, syringes for use with power-driven syringe pumps, syringes pre-filled with the injection by the manufacturer and syringes supplied with the injection as a kit for filling by a pharmacist.

NOTE 1 A second part of ISO 7886 is being prepared to cover syringes for use with power-driven syringe pumps.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this part of ISO 7886. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this part of ISO 7886 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 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times.*

3 Definitions

For the purposes of this part of ISO 7886, the following definitions apply.

3.1 nominal capacity: Capacity of the syringe as designated by the manufacturer.

NOTE 2 Examples are 1 ml, 5 ml, 50 ml.

3.2 graduated capacity: Volume of water at (20 ± 5) °C [or, for tropical countries (27 ± 5) °C] expelled from the syringe when the fiducial line on the piston traverses a given scale interval or intervals.

3.3 total graduated capacity: Capacity of the syringe at the graduation line furthest from the zero graduation line.

NOTE 3 The total graduated capacity may be equal to, or greater than, the nominal capacity.

3.4 maximum usable capacity: Capacity of the syringe when the piston is drawn back to its furthest functional position.

3.5 fiducial line: Line circumscribing the end of the piston for determining the capacity corresponding to any scale reading of the syringe.

4 Nomenclature

The nomenclature for components of hypodermic syringes for single use is shown in figure 1.