

Australian Standard<sup>®</sup>

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**Single-use syringes (sterile) for  
the injection of 100 units per  
millilitre insulin (U-100)**

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This Australian Standard was prepared by Committee HT/2, Hypodermic Equipment for Insulin Injection. It was approved on behalf of the Council of Standards Australia on 29 April 1992 and published on 22 June 1992.

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The following interests are represented on Committee HT/2:

Alfred Hospital, Vic.  
Australian Chamber of Commerce  
Australian Diabetes Society  
Australian Medical Association  
Department of Commercial Services, N.S.W.  
Department of Health, Housing and Community Services (Commonwealth)  
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Diabetes Australia  
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**Single-use syringes (sterile) for  
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## PREFACE

This Standard was prepared by the Standards Australia Committee on Hypodermic Equipment for Insulin Injection under the direction of the Multitechnics Standards Policy Board, to supersede AS 1077—1981, *Single-use 1 mL syringes (sterile) for the injection of 100 units per millilitre insulin (U-100)*. It has been prepared in a manner intended to make it suitable for adoption as a Therapeutic Goods Order under the Commonwealth of Australia Therapeutic Goods Act. If adopted, the Commonwealth of Australia may add or subtract requirements to this Standard as it sees fit.

This edition differs from the 1981 edition mainly in the following areas:

- (a) The inclusion of requirements for 0.5 mL and 0.3 mL syringes.
- (b) The alignment of dose accuracy requirements with those in ISO 8537.
- (c) The inclusion of requirements for multiple syringe packs.

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## STANDARDS AUSTRALIA

## Australian Standard

**Single-use syringes (sterile) for the injection of 100 units per millilitre insulin (U-100)**

**1 SCOPE** This Standard specifies requirements for 1 mL, 0.5 mL and 0.3 mL syringes, packed with or without needles and intended for use once only, solely for injection of insulin of strength 100 units per millilitre (U-100).

Syringes taking detachable needles have the 6 percent (Luer) fitting.

## NOTES:

- 1 Sterile hypodermic syringes specified in this Standard are intended for use immediately after filling and are not intended for containing insulin over extended periods.
- 2 Advisory information on alternative means for demonstrating compliance with this Standard is given in Appendix A.

**2 REFERENCED DOCUMENTS** The following documents are referred to in this Standard:

## AS

- 1199 Sampling procedures and tables for inspection by attributes
- 1386 Cleanrooms and clean workstations
- 1386.1 Part 1: Principles of clean space control
- 1399 Guide to AS 1199—Sampling procedures and tables for inspection by attributes
- 1600 Medical equipment—Conical fittings with a 6 percent (Luer) taper for syringes, needles and certain other medical equipment
- 1600.1 Part 1: General requirements
- 1946 Hypodermic equipment—Single-use needles (sterile) for general medical use
- 2134 Recommended practice for chemical analysis by atomic absorption spectrometry
- 2134.1 Part 1: Flame atomic absorption spectrometry
- 2134.2 Part 2: Graphite furnace spectrometry
- 2193 Methods for calibration and grading of force-measuring systems of testing machines
- 3900 Quality systems—Guide to selection and use
- 3904 Quality management and quality system elements
- 3904.1 Part 1: Guidelines
- 3904.2 Part 2: Guidelines for services

## BS

- 5736 Evaluation of medical devices for biological hazards
- 5736.4 Part 4: Method of test for intracutaneous reactivity of extracts from medical devices
- 5736.11 Part 11: Method of test for haemolysis

## ISO

- 6009 Hypodermic needles for single use—Colour coding for identification

## ISO/IEC

- Guide 44 General rules for ISO or IEC international third-party certification schemes for products

British Pharmacopoeia (BP), Vol. 2, Appendix XIVK, p. A183, 1988.

United States Pharmacopoeia (USP), XXII Monograph 85, 1990.

Therapeutic Goods Order No. 11 Standard for sterile therapeutic goods, Commonwealth of Australia

**3 DEFINITIONS** For the purpose of this Standard, the definitions below apply.

**3.1 Syringe**—a syringe without needle, a syringe with detachable needle attached, or a syringe with fixed needle, the plunger being inserted in the barrel of the syringe.

**3.2 Needle**—a detachable needle or a fixed needle. A detachable needle may be so designed as to minimize dead space.

**3.3 Fixed (in relation to a needle)**—a needle not designed to be detachable from a syringe.

**3.4 Detachable (in relation to a needle)**—a needle not bonded or permanently fixed to the syringe.

**3.5 Unit pack**—a pack containing a single unit and providing the microbiological barrier.

**3.6 Multiple syringe pack**—a pack containing more than one and not more than twelve syringes.

**3.7 Multiple pack**—a pack, not being a store pack, containing two or more unit packs or two or more multiple syringe packs.

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