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SINGLE-USE 1 mL SYRINGES (STERILE) FOR THE INJECTION OF 100 UNITS PER MILLILITRE INSULIN (U-100)

[Title allocated by the Defence Cataloguing Authority: SYRINGE, HYPODERMIC: SYRINGE AND NEEDLE, HYPODERMIC (Single-use, For U-100 Strength Insulin Injection)]

STANDARDS ASSOCIATION OF AUSTRALIA
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THE FOLLOWING SCIENTIFIC, INDUSTRIAL AND GOVERNMENTAL ORGANIZATIONS and departments were officially represented on the committee entrusted with the preparation of this standard:

Australian Chamber of Commerce

Australian Dental Standards Laboratory

Australian Diabetes Society

Australian Medical Association

Commonwealth and State Departments of Health

Confederation of Australian Industry

Diabetes Federation of Australia

Hospitals and Hospital Associations

New South Wales Government Stores Department

The Pharmacy Guild of Australia

This standard, prepared by Committee ME 12, Hypodermic Equipment for Insulin Injection, was approved on behalf of the Council of the Standards Association of Australia on 3 August 1981, and was published on 12 October 1981.

AUSTRALIAN STANDARD

SINGLE-USE 1 mL SYRINGES (STERILE) FOR THE INJECTION OF 100 UNITS PER MILLILITRE INSULIN (U-100)

AS 1077—1981

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PREFACE

This edition of this standard was prepared by the Association's Committee on Hypodermic Equipment for Insulin Injection under the direction of the Medical Materials and Equipment Standards Committee to supersede AS 1077—1980. It has been prepared in a manner intended to make it suitable for adoption as a Statutory Standard under the Federal Therapeutic Goods Act.

This edition differs from the 1980 edition mainly in the packaging and labelling requirements and also in a number of editorial amendments. There is also a revised method of test for toxicity, incorporating a control solution.

A separate standard for 0.5 mL U-100 strength insulin syringes marked in single units and suitable for paediatric use is being published as AS 2495.

Facilities for testing for compliance with this standard are available at the Australian Dental Standards Laboratory, 240 Langridge Street, Abbotsford, Vic., 3067.

This standard requires reference to the following standards:

AS 1386	Cleanrooms and Work-stations
AS 1600	Conical Fittings with 6 percent (Luer) Taper for Hypoderm[illegible] and Other Surgical Equipment*
AS 1615	Single-use Needles (Sterile) for Insulin Injection*
AS 2070	Plastics Materials for Food Contact Use
AS 2134	Code of Practice for the Chemical Analysi[illegible] [illegible]terials by Flame Atomic Absorption Spectroscopy
AS 2193	Methods for Calibration and Grading of [illegible]orce-measuring Systems of Testing Machines
AS K185	Colours for Specific Purposes

*In course of revision.

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STANDARDS ASSOCIATION OF AUSTRALIA

Australian Standard
for
SINGLE-USE 1 mL SYRINGES (STERILE) FOR THE INJECTION OF 100 UNITS PER MILLILITRE INSULIN (U-100)

1 SCOPE. This standard specifies requirements for 1 mL syringes, individually packed with or without needles and intended for use once only, solely for injection of 100 units per millilitre insulin. The syringes are graduated to 100 'units' in 2-unit intervals.

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

NOTES:

1. Sterile hypodermic syringes specified herein are intended for use immediately after filling and are not intended for containing insulin over extended periods.
2. Advisory information on sampling and assessing compliance with this standard is given in Appendix O.

2 DESCRIPTION OF SYRINGE.

NOTE: The terms in italic type are illustrated in Fig. 1.

The components of the syringe are the *plunger* and the *barrel*, and, if provided, the needle. The term *proximal* refers to the end of the plunger which protrudes from the barrel, and to the corresponding end of the barrel and syringe. The term *distal* refers to the end of the plunger, barrel or syringe opposite to the proximal end. The plunger is *fully inserted* when seated firmly but not under pressure against the distal end of the barrel. Outward projections at the proximal end of the barrel are termed the *flange*. The space enclosed by the inside walls of the barrel is termed the *lumen*.

Syringes taking a detachable needle have a *nozzle* for attaching the needle onto the distal end of the barrel. *Graduation lines* and numbering, which comprise the *scale*, are marked on the barrel. The graduation line nearest the distal end of the barrel is termed the *zero line*. The graduation line nearest the proximal end is termed the *capacity line*. The proximal end of the plunger is formed into a *push-button*. The distal end of the plunger (which is usually a resilient plug or ring, termed the *seal*) forms a zone of contact with the inside wall of the barrel. The distal edge of this zone of contact is termed the *fiducial line* and provides the reference position for setting the plunger against the scale.

3 DEFINITIONS. For the purpose of this standard, the following definitions apply:

3.1 Syringe—a syringe without needle, a syringe with detachable needle attached and 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.

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

3.4 Unit (in relation to packing)—a syringe with or without a needle complying with Clause 18.1.

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

3.6 Multiple pack—a pack, not being a store pack, containing two or more unit packs.

3.7 Store pack—a pack containing one or more multiple packs.

3.8 Unit (in relation to insulin)—the International Unit of insulin.

3.9 Water—purified water of the British Pharmacopoeia.

4 DIMENSIONS OF SYRINGE.

4.1 Length.

4.1.1 *Syringe with detachable needle.* If the syringe takes a detachable needle, the length of the syringe with the plunger fully inserted and any detachable needle removed (dimension A in Fig. 2) shall not exceed 115 mm.

4.1.2 *Syringe with fixed needle.* If the syringe has a fixed needle, the length of the syringe with the plunger fully inserted and the exposed length of the needle tube included (dimension F in Fig. 2) shall not exceed 136 mm.

4.2 Length of Projection of Plunger from Barrel. The length of projection of the fully inserted plunger from the barrel of the syringe (dimension B in Fig. 2) shall not be less than 10 mm.

5 REQUIREMENTS FOR BARREL.

5.1 Composition. The barrel of the syringe shall be made of materials which—

(a) are transparent or sufficiently translucent to afford good visibility of the fiducial line and any air/liquid interface in the barrel;

(b) do not affect the therapeutic efficacy of insulin when the syringe is used to inject a preparation of insulin; and

(c) comply with the appropriate Part(s) of AS 2070 for plastics materials for food contact use. The use of any plastics material not specified by the appropriate parts of AS 2070 for food contact use shall, in the first instance, be referred to the appropriate Regulatory Authority for evaluation. In addition, the plastics materials shall be able to withstand the sterilization procedure as stated on the pack by the manufacturer (see Clause 19.1).

5.2 Shape. The barrel shall be essentially cylindrical between the zero line and the flange.

5.3 Lumen. The lumen of the barrel shall, except for any widening at the proximal end, be essentially cylindrical between the cross-sectional planes of the zero line and the proximal end.