AS 1077 — 1980
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Australian Standard
1077 – 1980

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
Incorporated by Royal Charter

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

Federated Pharmaceutical Service Guild of Australia

Hospitals and Hospital Associations

New South Wales Government Stores Department

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AUSTRALIAN STANDARD

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

AS 1077—1980

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PREFACE

This standard was prepared under the direction of the Medical Materials and Equipment Standards Committee to supersede AS 1077—1973, in anticipation that U-100 strength insulin will be available for use in Australia in August 1980. The standard has been prepared in a manner intended to make it suitable for adoption as a statutory standard under the Federal Therapeutic Goods Act.

Consideration is also being given to a separate standard for 0.5 mL U-100 strength insulin syringes marked in single units which will be suitable for paediatric use.

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 Hypodermic 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 Analysis of Materials by Flame Atomic Absorption Spectroscopy

AS 2193 Methods for Calibration and Grading of Force-measuring Systems of Testing Machines

AS K185 Colours for Specific Purposes

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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 for 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 wihout 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. 3) 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 or Fig. 3) 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) if plastics materials, 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).