AS 1615 — 1980
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# Australian Standard 1615 – 1980

# SINGLE-USE NEEDLES (STERILE) FOR INSULIN INJECTION

STANDARDS ASSOCIATION OF AUSTRALIA
*Incorporated by Royal Charter*



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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

Federated Pharmaceutical Service Guild of Australia

Hospitals and Hospital Associations

New South Wales Government Stores Department

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AUSTRALIAN STANDARD

# SINGLE-USE NEEDLES (STERILE) FOR INSULIN INJECTION

## AS 1615—1980

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# PREFACE

This standard was prepared under the direction of the Medical Materials and Equipment Standards Committee, to supersede AS 1615—1974.

Unlike the 1974 edition, this standard specifies only one size of needle, 0.45 mm × 13 mm (SWG 26 × ½ in). New appendices deal with tests for particulate contamination, extractable metals, pyrogens, toxicity and sterility.

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

This standard makes reference to the following standards:

AS 1077 Single-use 1 mL Syringes (Sterile) for the Injection of 100 Units per Millilitre Insulin (U − 100)

AS 1094 Single-use Syringes (Sterile) for General Medical Use

AS 1157 Methods of Testing Materials for Resistance to Fungal Growth Part 7 — Resistance of Papers and Paper Products to Surface Fungal Growth

AS 1386 Cleanrooms and Work-stations

AS 1444 Wrought Alloy Steels of the AISI-SAE H and Standard Steel Types

AS 1600 Conical Fittings with 6 percent (Luer) Taper for Hypodermic and Other Surgical Equipment

AS 2134 Code of Practice for the Chemical Analysis of Materials by Flame Atomic Absorption Spectroscopy

AS G18 Wrought Alloy Steels of the BS 970 EN Series Type

and to the European Pharmacopoeia, the British Pharmacopoeia, and the United States Pharmacopoeia.

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STANDARDS ASSOCIATION OF AUSTRALIA

# Australian Standard
# for
# SINGLE-USE NEEDLES (STERILE) FOR INSULIN INJECTION

**1 SCOPE.** This standard specifies requirements for sterilized individually packed hypodermic needles intended for use once only solely for the injection of insulin. The needle tubes are 0.45 mm in nominal external diameter and 13 mm in length.* The needles have the 6 percent (Luer) fitting.

NOTE: Advisory information on sampling and assessing for compliance with this standard is given in Appendix O.

**2 DESCRIPTION OF NEEDLE.** The essential components of the needle are the needle tube and the hub. One end of the needle tube is bonded in the hub; the other end of the needle tube is bevelled and sharpened to form the point. The hub is hollow, forming a socket into which the nozzle of a syringe can be fitted. The space enclosed by the wall of the needle tube is termed the lumen.

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

**3.1 Unit**— a needle with any sheath attached in accordance with Clause 14.1 and any attached hub cover, as illustrated in Fig. 1.

**3.2 Unit pack** — a pack containing a single unit.

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

**3.4 Store pack** — a pack containing one or more multiple packs.

**3.5 Water** — purified water as in the British Pharmacopoeia.

**3.6 Needle sheath** — the removable protective cover.

**4 REQUIREMENTS FOR NEEDLE TUBE.**

**4.1 Composition.** The needle tube shall be made of stainless steel which is either—

(a) one of the martensitic steels specified for the En 56 series in AS G18 or one of the steels specified in Table 1.3 of AS 1444; or

(b) one of the austenitic steels specified for the En 58 series in AS G18 or one of the steels specified in Table 1.2 of AS 1444.

**4.2 Appearance.** When the needle is examined without magnification and with magnification of about 10 × —

(a) the needle tube shall appear straight, cylindrical, and of uniform wall thickness;

(b) the outside surface of the needle shall appear smooth and clean and shall exhibit no corrosion, pitting, tool marks, sinks, voids, or stress marks;

(c) the inside surface of the needle tube shall exhibit no corrosion, no extraneous matter other than a film of lubricant, and no obstruction to the flow of liquid; and

(d) the pointed end of the needle tube shall appear sharp and shall exhibit smooth sharpened surfaces on at least three aspects, and shall exhibit no barbs, hooks, feathered edges or other defects.

**4.3 Resistance to corrosion.** When the needle is tested in accordance with Appendix A, the needle tube shall not show signs of corrosion.

**4.4 Dimensions.**

(a) The length of the needle tube (dimension A in Fig. 1) shall be not less than 12 mm and not more than 14 mm.

(b) The external diameter of the needle tube shall be not less than 0.43 mm and not more than 0.47 mm.

(c) The internal diameter of the needle tube shall be not less than 0.25 mm.

(d) The angle of the point (angle $\theta$ in Fig. 2) shall be not greater than 15 degrees and not less than 9 degrees.

**4.5 Mechanical Properties.**

**4.5.1** *Stiffness.* When the needle is tested in accordance with Appendix B, the deflection of the needle tube shall not exceed 0.20 mm.

**4.5.2** *Resistance to bending.* When the needle is tested in accordance with Appendix C, the needle tube shall not fracture.

**4.5.3** *Elastic recovery.* When the needle is tested in accordance with Appendix D, the angle of permanent set of the needle tube shall not exceed 1 degree.

**5 REQUIREMENTS FOR HUB.**

**5.1 Composition.** The hub of the needle shall be made of material which does not affect the therapeutic activity of insulin when the needle is used to inject any preparation of insulin.

**5.2 Appearance.** When the needle is examined with a magnification of about 10 × —

(a) the surfaces of the hub shall exhibit no sinks, voids or stress marks, no detached or detachable material, no extraneous matter and no obstruction to the flow of liquid through the needle;

(b) the socket shall appear coaxial with the needle tube; and

(c) any projection of the needle tube into the socket shall not exceed 1.5 mm in length.

* Formerly 26 SWG × ½ in.