

Australian Standard™

**Reusable all-glass or metal-and-glass
syringes for medical use**

**Part 2: Design, performance
requirements and tests**



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 9 August 2005. This Standard was published on 31 October 2005.

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
Commonwealth Department of Health and Ageing
Federation of Sterilizing Research and Advisory Councils of Australia
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PREFACE

This Standard was prepared by the Standards Australia Committee HE-009, Hypodermic Equipment—General Medical, to supersede in part AS 1679—1974, *Glass syringes (Luer fittings) for general medical use*. 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 is identical with, and has been reproduced from ISO 595-2:1987, *Reusable all-glass or metal-and-glass syringes for medical use—Part 2: Design, performance requirements and tests*.

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

- (a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.
- (b) In the source text, ‘this International Standard’ and ‘this part of ISO 595’ should read ‘this Australian Standard’.
- (c) A full point should be substituted for a comma when referring to a decimal marker.

Reference to International Standards should be replaced by references to the following Australian or Australian/New Zealand Standards:

| <i>Reference to International Standard or other publication</i> | | <i>Australian/New Zealand Standard</i> | |
|---|---|--|---|
| 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 |

AUSTRALIAN STANDARD

Reusable all-glass or metal-and-glass syringes for medical use

Part 2: Design, performance requirements and tests

0 Introduction

This International Standard on reusable syringes for medical use comprises two parts: ISO 595-1 covers the dimensions and details of the scale and ISO 595-2 (this part of ISO 595) covers design, performance and test methods.

1 Scope and field of application

This part of ISO 595 specifies the design, performance and the corresponding test methods for reusable syringes having a graduated capacity from 1 to 100 ml, for general medical use.

This part of ISO 595 is applicable to syringes of all-glass and metal-and-glass construction.

2 References

ISO 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements.*

ISO 594-2, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings.*¹⁾

3 Materials

3.1 Glass

Soda glass shall not be used for the manufacture of syringes.

3.2 Metal

If a metal part is protected by means of an electroplated or other type of coating, the base metal shall be capable of passing the test specified in 6.3 in the absence of the coating.

4 Construction and assembly

4.1 General

4.1.1 The construction shall be such that the piston is completely removable from the barrel.

4.1.2 The nozzle shall be a male conical fitting with a 6 % (Luer) taper in accordance with ISO 594-1 and/or ISO 594-2.

4.1.3 On syringes having a capacity up to 2 ml, the nozzle shall be situated centrally on the barrel. On syringes having a capacity above 2 ml, the nozzle shall be situated either centrally or eccentrically on the barrel.

If the nozzle is situated eccentrically, the distance between the axis of the nozzle and the nearest point of the internal surface of the barrel shall be not greater than 4 mm and the nozzle axis shall be diametrically opposite the scale on the barrel.

4.1.4 In all cases, the axis of the nozzle shall be parallel with the axis of the barrel.

4.1.5 The bore of the nozzle shall be centrally situated in the nozzle.

4.1.6 A means of braking the piston shall be provided unless the barrel and packaging are marked to indicate that no means of braking is provided.

If a means of braking the piston is provided, it shall be such that when the syringe is held in a vertical position with the nozzle uppermost, the piston shall remain stationary and shall not slide down under its own weight.

The braking action shall be such as not to interfere unduly with the operation of the piston in the syringe.

1) At present at the stage of draft.