

AS/NZS 2485:1995

Australian/New Zealand Standard

**Medical equipment—Single-use
winged intravenous devices (sterile)
for general medical use**

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Australian/New Zealand Standard

Medical equipment—Single-use winged intravenous devices (sterile) for general medical use

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee HT/1, Hypodermic and Other Equipment for General Medical Use, to supersede AS 2485—1981, *Single-use winged intravenous devices (sterile) for general medical use*.

The objective of this Standard is to provide users with winged intravenous devices, (generally known as 'scalp vein units') that are safe to use from a biological, chemical and physical aspect.

The principal differences between this edition and the 1981 edition are as follows:

- (i) Biological and chemical testing have been aligned with tests for other medical devices which store or deliver intravenous fluids.
- (ii) The test for cytotoxicity, as given in Appendix J, is a suggested acceptable method, and is not a mandatory part of the Standard.
- (iii) Labelling requirements have been harmonized with that in Therapeutic Goods Order No. 37, *General requirements for labels for therapeutic devices*.

The terms 'normative' and 'informative' have been used in this Standard to define the application of the appendix to which they apply. A 'normative' appendix is an integral part of a Standard, whereas an 'informative' appendix is only for information and guidance.

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CONTENTS

	<i>Page</i>
1 SCOPE	5
2 REFERENCED DOCUMENTS	5
3 DESCRIPTION OF DEVICE	6
4 DEFINITIONS	6
5 CLASSIFICATION	6
6 DESIGNATION AND DIMENSIONS OF NEEDLE TUBE	6
7 POINT OF NEEDLE	7
8 MATERIALS	8
9 WORKMANSHIP	9
10 WING	9
11 DEAD SPACE	9
12 CONNECTING ADAPTOR	9
13 MECHANICAL STRENGTH AND INTEGRITY OF UNIONS	9
14 FLOW RATE	10
15 CLOSURE DEVICE	10
16 COLOUR CODING	10
17 STERILITY	10
18 PYROGENICITY	11
19 CYTOTOXICITY	11
20 EXTRACTABLE METALS	12
21 HAEMOLYTIC EFFECTS	12
22 INTRACUTANEOUS REACTIVITY	12
23 PARTICULATE CONTAMINATION	12
24 REDUCING (OXIDIZABLE) MATTER	12
25 NON-VOLATILE RESIDUE	12
26 ABSORBANCE	12
27 ALKYLENE OXIDE GAS RESIDUES	12
28 PACKAGING	12
29 MARKING	13

APPENDICES

A	RECOMMENDED METHOD OF TESTING FOR INCOMPATIBILITY BETWEEN WINGED INTRAVENOUS DEVICES AND INJECTION FLUIDS	14
B	METHOD FOR DETERMINING DEAD SPACE	15
C	METHOD FOR TESTING TYPE I DEVICES FOR LEAKAGE	17
D	METHOD FOR TESTING TYPE II DEVICES FOR LEAKAGE	18
E	METHOD FOR TESTING THE MECHANICAL STRENGTH OF UNIONS ..	19
F	METHOD FOR TESTING THE INTEGRITY OF UNIONS	20
G	METHOD FOR DETERMINING FLOW RATE	21
H	METHOD FOR TESTING THE CLOSURE DEVICE FOR LEAKAGE	23
I	METHOD OF TEST FOR PYROGENS (BACTERIAL ENDOTOXINS)	24
J	METHOD OF TEST FOR CYTOTOXICITY	26
K	METHOD OF TEST FOR EXTRACTABLE TRACE METALS	32
L	METHOD OF TEST FOR PARTICULATE CONTAMINATION	34
M	METHOD OF TEST FOR REDUCING (OXIDIZABLE) MATTER	37

	<i>Page</i>
N METHOD OF TEST FOR NON-VOLATILE RESIDUE	39
O METHOD OF TEST FOR ABSORBANCE	40
P METHOD OF TEST FOR ALKYLENE (ETHYLENE OR PROPYLENE) OXIDE GAS RESIDUES	41

Originated as AS 2485—1981.
Jointly revised and designated AS/NZS 2485:1995.

STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Medical equipment—Single-use winged intravenous devices (sterile) for general medical use**

1 SCOPE This Standard specifies requirements for sterilized winged devices for intravenous use.

NOTE: Materials to be used for the construction of sterile winged intravenous devices for single-use are not specified in detail as their selection will depend, to some extent upon the design, process of manufacture and method of sterilization employed by individual manufacturers. The materials should be compatible with injection fluids included in the European or other relevant pharmacopoeia and, where this is not the case, the attention of the user should be drawn to the exception by labelling the device pack.

It is not practicable to specify a universally acceptable method of test for incompatibility. However, a number of solvents and other fluids selected from pharmacopoeia to represent materials used in injections is provided in Appendix A together with a simple test which may be used to detect visible or functional incompatibility between a winged intravenous device and an injectable fluid.

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

AS

- 1094 Medical equipment—Single-use syringes (sterile) for general medical use
- 1449 Wrought alloy steels—Stainless and heat-resisting steel plate, sheet and strip
- 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
- 2145 Hypodermic equipment—Hypodermic needle tubing
- 2837 Wrought alloy steels—Stainless steel bars and semi-finished products
- 3753 Recommended practice for chemical analysis by ultraviolet/visible spectrophotometry

BS

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

BS/EN

- 30993 Biological evaluation of medical devices
- 30993.4 Part 4: Selection of tests for interactions with blood

British Pharmacopoeia (BP), Vol.2

United States Pharmacopoeia (USP), Monograph 85

United States Pharmacopoeia (USP), 87

United States Pharmacopoeia (USP), Monograph 161

Therapeutic Goods Order (TGO)—Standard for sterile therapeutic goods (Commonwealth of Australia)

Therapeutic Goods Order (TGO)—General requirements for labels for therapeutic devices (Commonwealth of Australia)

3 DESCRIPTION OF DEVICE The winged intravenous device shall comprise of a two-winged needle tubing assembly, a connecting tube supplied with a connecting adaptor and a closure device (see Figure 1).

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

4.1 Angle of point—the angle θ of the line from the point to the junction of the initial bevel and the full needle tube diameter, as illustrated in Figure 2.

4.2 Bore—the nominal internal dimension of the cannula.

4.3 Closure device—the component for securely closing the connecting adaptor.

4.4 Connecting adaptor—a female Luer fitting or an elastomeric injection diaphragm.

4.5 Connecting tube—the flexible tubing from the cannula or wing to the connecting adaptor.

4.6 Device—the winged needle assembly, connecting tube, connecting adaptor and the closure device, i.e. the intravenous device complete.

4.7 Length—the length of the needle tube from the tip of the tube to the joint with the wing.

4.8 Maximum wall thickness—half of the difference between the minimum bore and the upper limit of the nominal external diameter appropriate to the designated sizes as specified in Table 1.

4.9 Multiple pack—a pack containing a number of device packs.

4.10 Needle tube sheath—the removable protective cover.

4.11 Needle tubing

4.11.1 Standard needle tubing—needle tubing complying with AS 2145.

4.11.2 Thin-walled needle tubing—tubing having a wall thickness of at least 30% less than the maximum wall thickness of standard tubing.

4.12 Patient surface—the surface of the wing which is opposite to the ground angle of the point of the needle tube.

4.13 Point—the end of the needle tube which has been bevelled and sharpened.

4.14 Two-winged—a flexible flange attached to the needle tube to facilitate manipulation and securing of the needle tube.

4.15 Unit pack—a pack containing a single device.

4.16 Winged needle assembly—the flange and the needle tube.

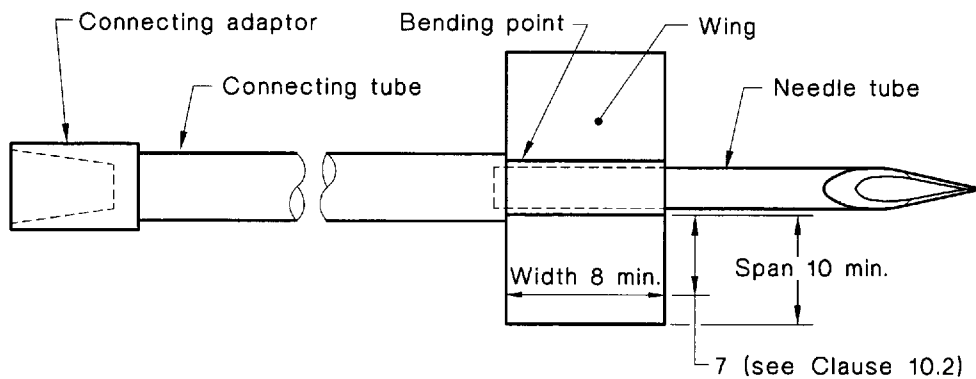
5 CLASSIFICATION For the purpose of this Standard, winged intravenous devices are classified as follows:

Type I—devices for continuous therapy.

Type II—devices for intermittent therapy (and incorporating an injection diaphragm).

NOTE: Both types can have standard needle tubing or thin-walled tubing.

6 DESIGNATION AND DIMENSIONS OF NEEDLE TUBE The designation and dimensions of needle tubes in the range appropriate to the Standard shall conform to the requirements of Table 1. The tolerance on the nominal lengths, as specified by the manufacturer, shall be ± 1.0 mm.



NOTES:

- 1 The diagram shows a typical winged intravenous device for the purpose of illustrating the relevant dimensions and terms, but the illustrated design of the winged intravenous device does not form part of the Standard and gives no preference to wing design.
- 2 Drawings are not to scale.

DIMENSIONS IN MILLIMETRES

FIGURE 1 ILLUSTRATION OF WINGED INTRAVENOUS DEVICE

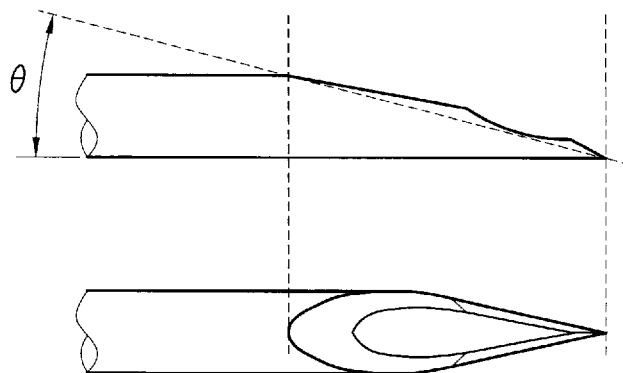


FIGURE 2 TYPICAL POINT OF NEEDLE TUBE

7 POINT OF NEEDLE

7.1 Angle of point The angle θ as illustrated in Figure 2 shall be either—

- (a) 12 ± 3 degrees; or
- (b) 18 ± 2 degrees.

NOTE: The angle in Item (a) is usually referred to as a regular or long bevel. The angle in Item (b) is usually referred to as a short bevel.

7.2 Finish of point When the needle tube is examined without magnification and with magnification of about 10 $\times$, the pointed end of the needle tube shall appear sharp and strong, shall exhibit smooth sharpened surfaces on at least two aspects, and shall exhibit no barbs, hooks, feathered edges or other defects.

TABLE 1
DESIGNATION AND DIMENSIONS OF NEEDLE TUBE

millimetres				
Designated size (nominal external diameter × length)	Nearest SWG number	Tolerance on nominal external diameter	Minimum bore	Maximum wall thickness for thin-walled tubing
0.36 × 9 to 20	28	±0.02	0.18	0.077
0.40 × 9 to 20	27	±0.02	0.20	0.077
0.45 × 9 to 20	26	±0.02	0.23	0.080
0.50 × 9 to 20	25	±0.03	0.23	0.110
0.63 × 15 to 20	23	±0.03	0.32	0.140
0.71 × 15 to 20	22	±0.04	0.39	0.140
0.80 × 15 to 25	21	±0.04	0.48	0.140
0.90 × 15 to 32	20	±0.04	0.56	0.140
1.00* × 15 to 32	19	+0.12	0.65	0.160
1.25 × 15 to 32	18	±0.05	0.77	0.190

* See AS 2145
NOTE: The lengths specified are indicative of existing sizes.

8 MATERIALS

8.1 General The materials of the fluid path from which the device is made shall—

- (a) not have any deleterious effect on blood, blood derivatives, other intravenous fluids, or substances added to blood or intravenous fluids before or during passage through the device;
- (b) not produce any local reaction or general toxic reaction in the recipient of fluids passed through the device; and
- (c) comply with the requirements of Clauses 18 to 27.

NOTE: The tests specified in Clauses 18 to 27 are manufacturing validation tests and not batch release tests.

8.2 Needle tube The needle tube shall be made of stainless steel which shall be one of the austenitic or martensitic steels specified in either AS 1449 or AS 2837.

8.3 Closure device

8.3.1 Type I devices The closure device shall be of plastics material, meeting the requirements of Clause 8.1.

8.3.2 Type II devices The closure device shall be of elastomeric material suitable for penetration by a needle, and shall comply with the requirements of Clause 8.1.

8.4 Connecting tube The connecting tube shall be of flexible material, clear enough to permit inspection of contents, and shall not interact with commonly used intravenous medicaments. It shall comply with the requirements of Clause 8.1.

8.5 Wing The wing shall be of non-toxic and non-irritant material which shall be flexible enough to be easily folded, yet rigid enough to allow full needle tube control.

9 WORKMANSHIP

9.1 Needle tube The needle tube shall comply with AS 2145.

9.2 Connecting tube The connecting tube shall be cylindrical, of uniform wall thickness and free from manufacturing defects. It shall be clear, appear clean and free from extraneous matter, inside and out, and shall comply with the requirements of Clause 13.1.

NOTE: The defects described in Clause 9.2 cannot be completely quantified. Where the presence or frequency of any of these are considered to be of concern, arrangements should be made between the purchaser and the manufacturer. This may be achieved by the provision of acceptable type samples or methods of test.

Where defects are present and the product is submitted for acceptance, the manufacturer should be able to demonstrate fitness for purpose.

10 WING

10.1 Form and shape The wings shall be large enough so that when folded in the vertical position, they offer the operator a firm secure grip.

NOTE: The span of the wing should be at least 10 mm measured from the bending point, and the width of the wing when measured at a point 7 mm from the needle tube should be at least 8 mm, as illustrated in Figure 1.

10.2 Relationship of needle tube to wing When the patient surface of the wing is laid on a flat surface, the needle tube shall—

- (a) not protrude by more than 3 mm beyond the junction of the wing and the connecting tube;
- (b) be such that the distance from the needle tube at the point of entry into the wing to the flat surface shall not exceed 1 mm;
- (c) lie essentially in the same plane as the wing with the bevel uppermost (see Note to Clause 7.1);
- (d) be within ± 15 degrees of the centre-line as illustrated in Figure 3(a);
- (e) either lie in the same plane as the wing with the bevel pointing upwards, or have a slight downward angle towards the flat surface without actually touching the surface; and
- (f) have a maximum deflection of 5 degrees as illustrated in Figure 3(b).

11 DEAD SPACE The maximum dead space of the needle tube, connecting tube and adaptor when a syringe is inserted for any size of needle shall not exceed 0.5 mL.

When tested in accordance with Appendix B, the dead space shall be within 0.1 mL of the dead space specified by the manufacturer.

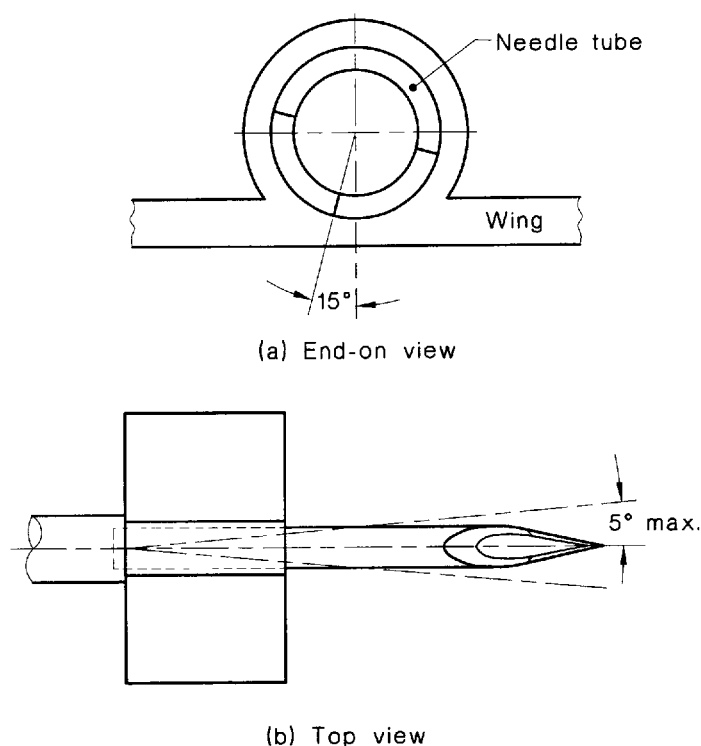
12 CONNECTING ADAPTOR When tested in accordance with Appendix C, there shall be no evidence of leakage between the connecting adaptor and the syringe for Type I devices.

When tested in accordance with Appendix D, there shall be no evidence of leakage between the connecting adaptor and the injection site, for Type II devices.

13 MECHANICAL STRENGTH AND INTEGRITY OF UNIONS

13.1 Mechanical strength When tested in accordance with Appendix E, the unions of the needle tube and wings, the wings and the connecting tube, and the connecting tube and connecting adaptor, shall not exhibit any loosening. The connecting tube itself shall not break during the test.

13.2 Integrity When the unions of the fluid pathway are tested for joint integrity in accordance with Appendix F, there shall be no leakage.



NOTES:

- 1 The diagrams show a typical winged intravenous device for the purpose of illustrating the relevant dimensions and terms, but the illustrated design of the winged intravenous device does not form part of the Standard and gives no preference to wing design.
- 2 Drawings are not to scale.

FIGURE 3 DIAGRAMMATIC REPRESENTATION OF RELATIONSHIP OF NEEDLE TUBE TO WING

14 FLOW RATE When determined in accordance with Appendix G, the minimum rate of flow of water as appropriate to the nominal external diameter of the needle tube, shall be as specified in Table 2.

15 CLOSURE DEVICE The closure device shall not leak. When tested in accordance with Appendix H, the closure device shall not show any evidence of bubbling or be blown off by a pressure of 20 kPa.

16 COLOUR CODING The colour coding shall relate to the nominal external diameter of the needle tube and be in accordance with the colour code specified in Table 3. Colour coding shall be applied to the winged needle assembly or part thereof or the connecting adaptor (or both).

17 STERILITY The winged intravenous device shall be sterile. When tested for sterility in accordance with Therapeutic Goods Order (TGO)—Standard for sterile therapeutic goods, the device shall comply with the criteria in that document.

NOTE: Manufacturers should ensure that their devices are capable of complying with the requirements of this TGO. Where a dispute may arise, this TGO will be the reference method of test.

TABLE 2
FLOW RATE OF NEEDLE TUBE

Nominal external diameter mm	Nearest SWG number	Minimum flow rate mL/min
0.36	28	1.5
0.40	27	1.6
0.45	26	1.6
0.50	25	1.6
0.63	23	2.9
0.71	22	8.2
0.80	21	13.5
0.90	20	23.0
1.00	19	32.0
1.25	18	47.0

TABLE 3
COLOUR CODING TO DENOTE THE EXTERNAL DIAMETER
OF THE NEEDLE TUBE

Nominal external diameter mm	Nearest SWG number	Colour coding	Munsell Atlas reference
0.36	28	Blue green	7.5 BG 5/8
0.40	27	Medium grey	N7
0.45	26	Brown	10 R 4/4
0.50	25	Orange	3.75 YR 6/12
0.63	23	Deep blue	2.5 PB 3/8
0.71	22	Black	N2.0
0.80	21	Deep green	2.5 G 4/8
0.90	20	Yellow	3.75 Y 8/14
1.00	19	Cream	10 YR 9/2
1.25	18	Pink	25 R 7/6

18 PYROGENICITY When tested in accordance with Appendix I, the winged intravenous device shall be non-pyrogenic.

NOTE: The use of either Method A (LAL Test) or Method B (Rabbit Pyrogen Test) in Appendix I is acceptable.

19 CYTOTOXICITY The winged intravenous device shall be non-cytotoxic. Appendix J gives an acceptable method of test for cytotoxicity.

NOTE: As the test for cytotoxicity is also a manufacturing validation test, and not a batch release test, this test or other acceptable tests need to be carried out whenever materials or other changes could affect the final product. On batches of identical formulation and manufacturing process, only representative batches need be tested.

20 EXTRACTABLE METALS When the winged intravenous device is tested in accordance with Appendix K, the device shall not contain more than 10 µg extractable cadmium, and shall not contain in total more than 100 µg of extractable barium, chromium, copper, lead and tin.

21 HAEMOLYTIC EFFECTS

NOTE: Where appropriate, guidance on testing for haemolysis is given in BS/EN 30993.4.

22 INTRACUTANEOUS REACTIVITY When the winged intravenous device is tested in accordance with BS 5736: Part 4, the mean numerical rating for the test solution shall not differ from that of the control.

23 PARTICULATE CONTAMINATION When tested in accordance with Appendix L, the winged intravenous device shall not have more than two particles greater than 20 µm in size per millilitre of washing solution.

24 REDUCING (OXIDIZABLE) MATTER When the winged intravenous device is tested in accordance with Appendix M, the mass of reducing substances, expressed as milligrams of sodium thiosulfate per device shall be less than 1.58 mg.

25 NON-VOLATILE RESIDUE When determined in accordance with Appendix N, the non-volatile residue of the winged intravenous device shall not exceed 8.5 mg.

26 ABSORBANCE When determined in accordance with Appendix O, the extract solution of the winged intravenous device shall not show an absorbance greater than 0.1 over the range 250 nm to 320 nm.

27 ALKYLENE OXIDE GAS RESIDUES When tested in accordance with Appendix P, where the winged intravenous device is treated with ethylene oxide gas (or a related alkylene oxide gas), the residues in the plastics material shall not exceed 25 µg/g alkylene oxide gas, 25 µg/g alkylene chlorohydrin and 250 µg/g alkylene glycol.

28 PACKAGING

28.1 General Each winged intravenous device shall be individually packaged. Device packs shall be contained in multiple packs. Multiple packs may be contained in store packs.

A sheath protecting the needle tube shall be provided. It shall be of adequate length to cover the point of the needle tube. The sheath shall have a tight enough fit so that it will not work loose during normal handling and transit, but can be readily removed by the fingers at the time of use.

28.2 Unit pack The requirements for the packaging of the device are as follows:

- (a) Each device shall be contained individually in a unit pack which—
 - (i) permits exposure of the device to the sterilizing agent, and maintains the sterility of the device under normal conditions of storage, handling and transport;
 - (ii) cannot be opened without obviously damaging the device pack or its sealing; and
 - (iii) can be easily opened without dislodging the protective sheath of the needle tube and without contaminating the contents of the pack.

NOTE: Ease of opening should also be possible even when wearing examination or surgical gloves.

- (b) The device pack shall show no evidence of mould growth when examined under 10× magnification.

28.3 Multiple pack A convenient number of unit packs shall be contained in a multiple pack. Multiple packs should be sufficiently robust so as to protect the contents during normal storage and use. If the device packs are packed in the multiple pack before sterilization, the packaging material shall permit exposure of the devices to the sterilizing agent.

28.4 Store pack A convenient number of multiple packs may be contained in a store pack. Store packs, where provided, should be sufficiently robust so as to protect the contents from damage during normal storage, transport and handling. If the multiple packs are packed in the store pack before sterilization, the packaging material shall permit exposure of the devices to the sterilizing agent.

29 MARKING

29.1 On the device The following information shall legibly appear on each device:

- (a) The name or registered trade name or mark of the manufacturer of the device.
- (b) The nominal external diameter of the needle tube, in millimetres, or appropriate colour coding in accordance with Clause 16.

29.2 On the unit pack The unit pack shall be marked in accordance with the Therapeutic Goods Order (TGO)—General requirements for labels for therapeutic devices. In addition the following shall be marked:

- (a) The nominal external diameter of the needle tube and the length in millimetres in accordance with Table 1.
- (b) The volume of dead space, expressed in millilitres.
- (c) If the needle tube is thin walled, a statement to that effect.

29.3 On the multiple pack The multiple pack shall be marked in accordance with the Therapeutic Goods Order (TGO)—General requirements for labels for therapeutic devices. In addition, the following shall be marked:

- (a) The nominal external diameter and length of the needle tube, in millimetres.
- (b) Any conditions of storage recommended by the manufacturer.

NOTE: Manufacturers making a statement of compliance with this Australian Standard on a product, packaging, or promotional material related to that product are advised to ensure that such compliance is capable of being verified.