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МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ

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

Part 2: Design, performance requirements and tests

Seringues réutilisables en verre ou en verre et métal à usage médical —

Partie 2: Conception, performances et essais

Reference number
ISO 595-2 : 1987 (E)

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work.

Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 595-2 was prepared by Technical Committee ISO/TC 84, *Syringes for medical use and needles for injections*.

Together with ISO 595-1 : 1986 it cancels and replaces ISO Recommendation R 595 : 1967, of which it constitutes a technical revision.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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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.

4.2 All-glass syringes

4.2.1 When examined with normal or corrected vision, the inside of the barrel and the outside of the piston shall have a smooth finish and shall be free from surface defects, such as pits, air lines and high spots.

NOTE — The surface may be ground.

4.2.2 The glass barrel shall be transparent when wet.

4.2.3 The open end of the barrel shall be slightly bell-mouthed to ensure easy entry of the piston.

The open end of the barrel shall have a flange which shall act as a finger grip. The flange shall be manufactured so that it prevents the syringe from rolling when placed on a flat surface inclined at 10° to the horizontal. The scale shall be readable when the syringe is resting on a level surface.

4.2.4 The end of the piston which is inserted into the barrel shall have a clearly defined edge to serve as a fiducial line; if this end is bevelled, the edge of the piston in contact with the barrel shall be taken as the fiducial line.

NOTES

1 The end of the piston and the bottom of the barrel should be shaped so as to minimize dead space.

2 The piston may be either hollow or solid.

4.2.5 The end of the piston that protrudes from the barrel shall be shaped to form a push-button with a flat or concave surface.

4.2.6 If the syringe has a metal nozzle, the nozzle shall be attached so that, when tested in accordance with 6.6, no coloured water shall be visible between the nozzle and the barrel.

4.3 Metal-and-glass syringes

4.3.1 The barrel shall be made of glass; the detachable cap, the nozzle, the plunger and push-button shall be made of metal; and the piston shall be made of metal or ceramic material.

4.3.2 When examined with normal or corrected vision, the inside of the barrel shall have a smooth finish and shall be free from surface defects, such as pits, air lines and high spots.

4.3.3 The glass barrel shall be transparent when wet.

4.3.4 A flat surface shall be provided on the detachable cap or on the nozzle end of the syringe in such a position that the syringe will not roll when it is placed on a surface inclined at 10° to the horizontal.

The flat surface shall be such that when the syringe rests on a level surface, the scale will be readable.

5 Performance requirements

5.1 Resistance to thermal shock

When tested in accordance with 6.1, there shall be no fracture of the barrel or other damage to the barrel or the attached fittings.

5.2 Resistance to dry heat

When tested in accordance with 6.2, the assembled syringe shall operate satisfactorily. There shall be no signs of fracture in glass components or deterioration of metal components and markings.

5.3 Resistance to corrosion

When tested in accordance with 6.3, the assembled syringe shall operate satisfactorily and

— neither the glass nor metal parts of the syringe shall show signs of attack;

— the markings shall not show deterioration in their intensity.

5.4 Freedom from leakage between piston and barrel

When tested in accordance with 6.4, no leakage of water between the piston and the barrel shall be visible.

5.5 Permanence of markings

When tested in accordance with 6.5, the markings shall remain legible.

5.6 Freedom from entrapped fluid

When tested in accordance with 6.6, no coloured water shall be visible in the joints between metal and glass.

5.7 Freedom from striae and strain

When examined in accordance with 6.7, glass components shall be free from striae and strain.

6 Test methods

6.1 Test procedure for resistance to thermal shock

Dismantle the syringe and bring the components to room temperature.

Plunge the components into water at 99 ± 1 °C.

After 30 s, remove the components from water at 99 ± 1 °C and plunge them into water at room temperature.

Remove the components from the water and examine them with normal or corrected vision for fractures and damage.

6.2 Test procedure for resistance to dry heat

Dismantle the syringe and bring the components to room temperature. Place them in an oven at the same temperature.

Increase the temperature of the oven to 180 $^{+5}_{0}$ °C and maintain this temperature for 30 min.

Remove the components and allow them to cool to room temperature.

With normal or corrected vision, examine the glass components for fractures and all components for damage and for deterioration of the markings. Re-assemble the syringe and check for satisfactory operation.

6.3 Test procedure for resistance to corrosion

Dismantle the syringe and subject the components to the following treatments:

a) autoclave for 30 min in saturated steam at 121 ± 5 °C;

b) immerse for 30 min in water at 99 ± 1 °C;

c) immerse for 30 min in aqueous saline solution containing 9 g of sodium chloride per litre at 99 ± 1 °C.

Following the above treatments, allow the syringe components to cool to room temperature. Rinse them in clean water and examine them with normal or corrected vision for signs of deterioration.

6.4 Test procedure for leakage between piston and barrel

Fill the syringe to its nominal capacity with distilled water.

Connect the syringe to a reference female conical fitting as specified in ISO 594.

Apply a force to the piston that will generate a pressure of

a) 300 kPa for syringes having a capacity from 1 to 10 ml; or

b) 200 kPa for syringes having a capacity greater than 10 ml and less than or equal to 30 ml; or

c) 150 kPa for syringes having a capacity greater than 30 ml.

Maintain this pressure for 10 s.

Examine the syringe for leakage of water between piston and barrel.

6.5 Test procedure for permanence of markings

Immerse the syringe completely in an open beaker containing a hydrochloric acid solution, $c(\mathrm{HCl})$ = 0,01 mol/l.

Autoclave the beaker and its contents in saturated steam at 121 ± 5 °C for 30 min.

Repeat the autoclaving once more after the contents have cooled down to room temperature.

Examine the markings with normal or corrected vision.

6.6 Test procedure for entrapped fluid

Partially fill the syringe with a brightly coloured dye solution in water and apply a force to the piston that will generate a pressure of

a) 300 kPa for syringes having a capacity from 1 to 10 ml; or

b) 200 kPa for syringes having a capacity greater than 10 ml and less than or equal to 30 ml; or

c) 150 kPa for syringes having a capacity greater than 30 ml.

Remove the coloured water from the barrel, remove the piston and rinse the barrel with water.

Immediately after rinsing, examine the joints between the metal and glass with normal or corrected vision through the inside of the barrel from the open end.

6.7 Test procedure for freedom from striae and strain

Examine the glass components for the presence of striae and strain by means of a polariscope.

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