INTERNATIONAL STANDARD

ISO 9626

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Stainless steel needle tubing for manufacture of medical devices

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical

Reference number
ISO 9626:1991(E)

Contents

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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. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 9626 was prepared by Technical Committee ISO/TC 84, *Syringes for medical use and needles for injections*, Sub-Committee SC 1, *Syringes and needles for single use*.

Annexes A, B, C, D and E form an integral part of this International Standard.

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Stainless steel needle tubing for manufacture of medical devices

1 Scope

This International Standard specifies the dimensions, surface and mechanical properties of normal- and thin-walled tubing of designated metric sizes 3,4 mm to 0,3 mm, and of extra-thin-walled tubing of designated metric sizes 2,1 mm to 0,6 mm.

Because no data are available, this International Standard does not specify stiffness properties for extra-thin-walled tubing of designated metric sizes 0,8 mm; 0,9 mm; 1,2 mm; 1,4 mm; 1,8 mm and 2,1 mm.

This International Standard applies to rigid stainless steel needle tubing suitable for use in the manufacture of hypodermic needles and other medical devices primarily for human use.

It does not apply to flexible stainless steel tubing because the mechanical properties differ from those specified for rigid tubing in this International Standard. However, manufacturers and purchasers of flexible tubing are encouraged to adopt the dimensional specifications given in this International Standard.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 683-13:1986, *Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

3 Materials

Tubing shall be made from austenitic stainless steel of types 10, 11, 16, 20, 21 or 23 in accordance with ISO 683-13.

4 Surface finish

When examined by normal or corrected vision, the outside surface of the tubing shall be smooth and free from defects.

5 Cleanliness

When examined by normal or corrected vision, the surfaces of the tubing shall be free from metal soil and processing agents.

6 Limits for acidity and alkalinity

When tested in accordance with annex A, an extract of the tubing prepared in accordance with annex B shall, when corrected for the volume of titrant required for the control fluid, require not more than 0,04 ml of sodium hydroxide solution or not more than 0,12 ml of hydrochloric acid solution to reach the end-point of the titration.

7 Size designation

Tubing shall be designated by the nominal outside diameter expressed in millimetres (i.e. the designated metric size) and by its category, i.e. normal-walled, thin-walled, or extra-thin-walled.

8 Dimensions

The dimensions of tubing shall be as given in table 1.

9 Stiffness

When tested in accordance with annex C, the tubing shall show a deflection not greater than the relevant value given in table 2.

Table 1 — Dimensions of tubing

Dimensions in millimetres

Designated metric size	Range of outside diameters[1]		Inside diameter of tubing				
			Normal-walled		Thin-walled		Extra-thin-walled
	min.	max.	min.	max.	min.	max.	min.
0,3	0,298	0,320	0,133	0,164	0,165	—	—
0,33	0,324	0,351	0,133	0,189	0,190	—	—
0,36	0,349	0,370	0,133	0,189	0,190	—	—
0,4	0,400	0,420	0,184	0,240	0,241	—	—
0,45	0,440	0,470	0,232	0,291	0,292	—	—
0,5	0,500	0,530	0,232	0,291	0,292	—	—
0,55	0,550	0,580	0,280	0,342	0,343	—	—
0,6	0,600	0,650	0,317	0,359	0,360	0,379	0,380
0,7	0,698	0,730	0,390	0,439	0,440	0,459	0,460
0,8	0,800	0,830	0,490	0,529	0,530	0,549	0,550
0,9	0,860	0,920	0,560	0,609	0,610	0,629	0,630
1,1	1,030	1,100	0,648	0,749	0,750	0,849	0,850
1,2	1,200	1,300	0,790	0,909	0,910	1,040	1,041
1,4	1,400	1,510	0,950	1,155	1,156	1,243	1,244
1,6	1,600	1,690	1,100	1,282	1,283	1,389	1,390
1,8	1,750	1,900	1,300	1,459	1,460	1,559	1,560
2,1	1,950	2,150	1,500	1,599	1,600	1,726	1,727
2,4	2,300	2,500	1,700	1,955	1,956	—	—
2,7	2,650	2,850	1,950	2,234	2,235	—	—
3	2,950	3,150	2,200	2,463	2,464	—	—
3,4	3,300	3,500	2,500	2,818	2,819	—	—

1) Needle tubing should have a tolerance of ± 0,01 mm on the actual outside diameter.

Table 2 — Conditions for stiffness test

Designated metric size	Normal-walled tubing			Thin-walled tubing			Extra-thin-walled tubing		
	Span	Bending force	Maximum deflection	Span	Bending force	Maximum deflection	Span	Bending force	Maximum deflection
mm	mm ± 0,1	N ± 0,1	mm	mm ± 0,1	N ± 0,1	mm	mm ± 0,1	N ± 0,1	mm
0,3	5	5,5	0,40	5	5,5	0,45	—	—	—
0,33	5	5,5	0,32	5	5,5	0,37	—	—	—
0,36	5	5,5	0,25	5	5,5	0,30	—	—	—
0,4	9,5	5,5	0,60	7,5	5,5	0,65	—	—	—
0,45	10	6	0,56	10	5,5	0,61	—	—	—
0,5	10	7	0,38	10	7	0,43	—	—	—
0,55	10	10	0,50	10	10	0,55	—	—	—
0,6	12,5	10	0,40	12,5	10	0,45	12,5	10	0,50
0,7	15	10	0,45	15	10	0,50	15	10	0,55
0,8	15	15	0,41	15	15	0,50	1)	1)	1)
0,9	17,5	15	0,48	17,5	15	0,65	1)	1)	1)
1,1	25	10	0,45	25	10	0,55	25	10	0,65
1,2	25	20	0,45	25	20	0,55	1)	1)	1)
1,4	25	22	0,45	25	22	0,55	1)	1)	1)
1,6	25	22	0,25	25	22	0,30	25	22	0,34
1,8	25	25	0,35	25	25	0,45	1)	1)	1)
2,1	30	40	0,40	30	40	0,50	1)	1)	1)
2,4	40	40	0,38	40	40	0,65	—	—	—
2,7	40	50	0,31	40	50	0,45	—	—	—
3	50	50	0,41	50	50	0,55	—	—	—
3,4	50	60	0,32	50	60	0,46	—	—	—

1) No data are available and therefore this international Standard does not specify stiffness properties for these sizes of tubing.

10 Resistance to breakage

When tested in accordance with annex D, the tubing shall not break.

11 Resistance to corrosion

When tested in accordance with annex E, the immersed half of the tubing shall show no evidence of corrosion resulting from the test.

Table 3 — Conditions for resistance to breakage test

Dimensions in millimetres

Designated metric size	Distance between rigid support and point of application of bending force (± 0,1)
0,3	8
0,33	8
0,36	8
0,4	8
0,45	10
0,5	10
0,55	12,5
0,6	15
0,7	17,5
0,8	20
0,9	25
1,1	27,5
1,2	30
1,4	31,5
1,6	31,5
1,8	31,5
2,1	31,5
2,4	31,5
2,7	31,5
3	31,5
3,4	31,5

Annex A
(normative)

Determination of acidity or alkalinity of tubing

A.1 Principle

An extract of the tubing is titrated with either acid or alkali to an end point using Tashiro's indicator.

A.2 Reagents

A.2.1 Tashiro's indicator (Screened methyl red).

Dissolve 0,2 g of methyl red and 0,1 g of methylene blue in ethanol 95 % (V/V) and make up to 100 ml.

A.2.2 Solution of sodium hydroxide,
c(NaOH) = 5 mmol/l (analytical grade reagent) in distilled or deionized water of grade 3 in accordance with ISO 3696.

A.2.3 Solution of hydrochloric acid,
c(HCl) = 5 mmol/l (analytical grade reagent) in distilled or deionized water of grade 3 in accordance with ISO 3696.

A.3 Apparatus

Selection of borosilicate glassware of class B for titrimetric determinations.

A.4 Procedure

A.4.1 Add 0,1 ml of indicator solution (A.2.1) to 20 ml of extract (prepared in accordance with annex B) in a titration flask.

A.4.2 If the colour of the solution in A.4.1 is violet, titrate with sodium hydroxide solution (A.2.2) until the colour changes to grey.

A.4.3 If the colour of the solution in A.4.1 is green, titrate with hydrochloric acid solution (A.2.3) until the colour changes to grey.

A.4.4 Record the volume of acid or alkali solution added.

A.4.5 Repeat A.4.1 to A.4.4, using 20 ml of control fluid (see B.3.2) in place of the extract.

A.4.6 Calculate from the results obtained in A.4.4 and A.4.5 the net volume of titrant that was required to neutralize the substances extracted from the needle tubing.

A.5 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the tubing;

b) whether the tubing was of normal-, thin-, or extra-thin-walled type;

c) the volume, expressed in millilitres, of sodium hydroxide solution or hydrochloric acid solution as calculated in A.4.6, stating also which substance;

d) the date of testing.

Annex B
(normative)

Method of preparation of extracts

B.1 Principle

The tubing is immersed in water in order to extract soluble materials.

B.2 Apparatus and reagents

B.2.1 Freshly distilled or deionized water, of grade 3 in accordance with ISO 3696.

B.2.2 Selection of laboratory borosilicate glassware.

B.3 Procedure

B.3.1 Immerse 3 g of tubing, cut to appropriate length if necessary, in 250 ml of water (B.2.1) in a suitable container made from borosilicate glass (B.2.2). Maintain the water and tubing at a temperature of (37 $^{+3}_{0}$) °C for 1 h. Then remove the tubing.

B.3.2 Prepare the control fluid by following the procedure given in B.3.1, but omitting the tubing.

Annex C
(normative)

Test method for stiffness of tubing

C.1 Principle

A specified force is applied to the centre of the specified length of tubing, which is supported at both ends, and the amount of deflection measured.

C.2 Apparatus

C.2.1 Stiffness testing apparatus, capable of applying a force of up to 60 N downwards normal to the tubing with an accuracy of $\pm$ 0,1 N, by means of a plunger having a lower end in the form of a blunt wedge formed by two plane surfaces inclined at 60° to one another and a cylindrical surface of radius of curvature 1 mm and length at least 5 mm. An example of a suitable apparatus is illustrated in figure C.1.

C.2.2 Equipment, capable of measuring the deflection of the tubing to the nearest 0,01 mm.

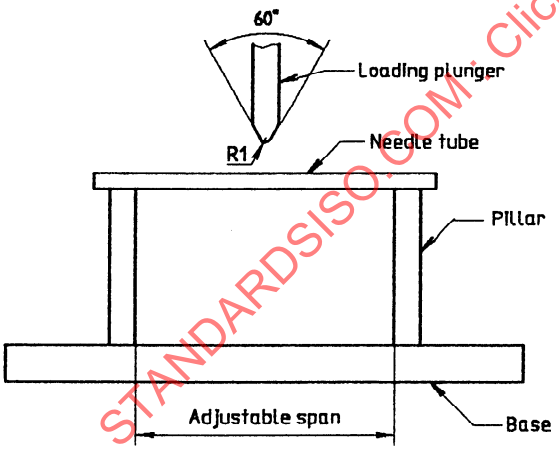

Figure C.1 — Apparatus for stiffness test

C.3 Procedure

C.3.1 Place the tubing on the stiffness testing apparatus (C.2.1) and adjust the tubing and the stiffness testing apparatus so that

a) the span is as given in table 2 for the designated metric size of the tubing; and

b) the bottom surface of the plunger is at the centre of the span; and

c) the tubing is normal to the supporting members and the loading plunger, and the centre of the tubing is at the centre of the span.

C.3.2 By means of the plunger, apply downwards at a rate of 1 mm/min to the tubing the bending force given in table 2 for the designated metric size of the tubing.

C.3.3 Measured and record (C.2.2) to the nearest 0,01 mm the deflection of the tubing at the point of application of the force.

C.4 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the tubing;

b) whether the tubing was of normal-, thin-, or extra-thin-walled type;

c) the measured deflection, expressed in millimetres to the nearest 0,01 mm;

d) the date of testing.

Annex D
(normative)

Test method for resistance of tubing to breakage

D.1 Principle

One end of the tubing is firmly fixed, and a force applied to the tubing at a specified distance from the point of fixation, so as to bend the tubing through a specified angle, first in one direction and then in the opposite direction, for a specified number of cycles.

D.2 Apparatus

D.2.1 Support and device for fixing the tubing.

D.2.2 Equipment, capable of applying a force to the tubing sufficient to bend it through an angle of up to 25°.

D.3 Procedure

D.3.1 Rigidly fix one end of the tubing in the support (D.2.1).

D.3.2 Apply (D.2.2), at the distance given in table 3, a force of sufficient magnitude to cause the tubing to bend in one plane through an angle of 25° for normal-walled tubing, 20° for thin-walled tubing, or 15° for extra-thin-walled tubing.

D.3.3 Apply the force in the reverse direction so as to cause the tubing to bend through the same angle in the reverse direction.

D.3.4 Perform 20 complete cycles of reversal of force at a rate of 0,5 Hz and examine the tubing visually for breakage.

D.4 Test report

The test report shall contain at least the following information:

a) the identity and designated metric size of the tubing;

b) whether the tubing was of normal-, thin- or extra-thin-walled type;

c) whether the tubing broke during the test;

d) the date of testing.