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.