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ISO 9626

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AMENDMENT 1
2001-06-01

Stainless steel needle tubing for the manufacture of medical devices —

AMENDMENT 1

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

iTeh **STANDARD PREVIEW**
AMENDEMENT 1
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ISO 9626:1991/Amd 1:2001

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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.

Attention is drawn to the possibility that some of the elements of this Amendment may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to International Standard ISO 9626:1991 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*, Subcommittee SC 1, *Syringes, needles and intravascular catheters for single use*.

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Introduction

The purposes of this amendment are to:

- a) add specifications for normal- and thin-walled tubing of metric sizes 0,2 mm, 0,23 mm and 0,25 mm to reflect the introduction of thinner tubing to allow greater comfort when injecting, particularly for infants and in paediatric use;
- b) add minimum inside diameters for thin-walled tubing of metric sizes 0,3 mm to 0,36 mm, as these data are now available;
- c) revise the maximum outside diameter of 0,6 mm metric size tubing to reflect current manufacturing practice;
- d) delete the maximum inside diameter of all types of tubing, as this value is not needed to discriminate between normal-, thin- and extra-thin-walled tubing;
- e) revise the means of specifying the steels to be used, as a result of the withdrawal of ISO 683-13.

For clarity in this amendment, the revised values in the new Tables 2, 3 and 4 are given in **boldface type**.

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Stainless steel needle tubing for the manufacture of medical devices —

AMENDMENT 1

Page 1, Scope

Replace the first paragraph by the following:

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

Page 1, Normative references

Delete the reference to ISO 683-13. Add the following normative references:

“ISO/TR 15510:1997, *Stainless steels — Chemical composition*.”

EN 10088-1:1995, *Stainless steels — Part 1: List of stainless steels*.”

Page 1, clause 3

[ISO 9626:1991/Amd 1:2001](https://standards.iteh.ai/catalog/standards/sist/f5573c22-5c6f-4e01-9f7d-73706/iso-9626-1991-amd-1-2001)

[https://standards.iteh.ai/catalog/standards/sist/f5573c22-5c6f-4e01-9f7d-](https://standards.iteh.ai/catalog/standards/sist/f5573c22-5c6f-4e01-9f7d-73706/iso-9626-1991-amd-1-2001)

Replace existing clause 3 with the following: [73706/iso-9626-1991-amd-1-2001](https://standards.iteh.ai/catalog/standards/sist/f5573c22-5c6f-4e01-9f7d-73706/iso-9626-1991-amd-1-2001)

“3 Materials

Tubing shall be made of austenitic stainless steel of one of the designated types given in Table 1 or any of the corresponding designations given in ISO/TR 15510, Table 2.”

Add the following new Table 1:

Table 1 — Types of stainless steel for needle tubing

Designation in ISO/TR 15510:1997 and EN 10088-1:1995	Line number in Tables 1 and 2 of ISO/TR 15510:1997	Corresponding type in ISO 9626:1991 and ISO 683-13:1986 (for information only)
X2CrNi 18-9	1	10
X5CrNi 18-9	6	11
X6CrNiNb 18-10	17	16
X5CrNiMo 17-12-2	26	20
X6CrNiMoTi 17-12-2	28	21
X6CrNiMoNb 17-12-2	29	23

In the first sentence, replace "table 1" with "Table 2". Delete existing Table 1 and replace with new Table 2 below. Changes are shown in boldface type.

Table 2 — Dimensions of tubing

Dimensions in millimetres

Designated metric size	Gauge size ¹⁾	Range of outside diameters		Inside diameter of tubing		
		min.	max.	Normal-walled	Thin-walled	Extra-thin-walled
				min.	min.	min.
0,2	33	0,203	0,216	0,089	0,105	—
0,23	32	0,229	0,241	0,089	0,105	—
0,25	31	0,254	0,267	0,114	0,125	—
0,3	30	0,298	0,320	0,133	0,165	—
0,33	29	0,324	0,351	0,133	0,190	—
0,36	28	0,349	0,370	0,133	0,190	—
0,4	27	0,400	0,420	0,184	0,241	—
0,45	26	0,440	0,470	0,232	0,292	—
0,5	25	0,500	0,530	0,232	0,292	—
0,55	24	0,550	0,580	0,280	0,343	—
0,6	23	0,600	0,673	0,317	0,370	0,460
0,7	22	0,698	0,730	0,390	0,440	0,522
0,8	21	0,800	0,830	0,490	0,547	0,610
0,9	20	0,860	0,920	0,560	0,635	0,687
1,1	19	1,030	1,100	0,648	0,750	0,850
1,2	18	1,200	1,300	0,790	0,910	1,041
1,4	17	1,400	1,510	0,950	1,156	1,244
1,6	16	1,600	1,690	1,100	1,283	1,390
1,8	15	1,750	1,900	1,300	1,460	1,560
2,1	14	1,950	2,150	1,500	1,600	1,727
2,4	13	2,300	2,500	1,700	1,956	—
2,7	12	2,650	2,850	1,950	2,235	—
3,0	11	2,950	3,150	2,200	2,464	—
3,4	10	3,300	3,500	2,500	2,819	—

1) For information only.

Page 2, clause 9

In the first sentence, replace "table 2" with "Table 3".

Page 3, clause 9

Delete existing Table 2 and replace with new Table 3 below. Changes are shown in boldface type.

Table 3 — 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 ± 0,1	N ± 0,1	mm	mm ± 0,1	N ± 0,1	mm	mm ± 0,1	N ± 0,1	mm
0,2	5	1,2	0,35	5	1,2	0,4	—	—	—
0,23	5	2	0,35	5	2	0,4	—	—	—
0,25	5	2,8	0,35	5	2,8	0,4	—	—	—
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.

Page 3, clause 10

Add the phrase "and Table 4" to the first sentence so that the text reads:

"When tested in accordance with annex D and Table 4, the tubing shall not break."

Page 4

Replace existing table 3 with Table 4 below. Changes are shown in boldface type.

Table 4 — Conditions for resistance to breakage test

Designated metric size	Distance between rigid support and point of application of bending force
	mm ± 0,1
0,2	6
0,23	6
0,25	8
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

Page 7, annex C, subclause C.3.1 a)

Delete the words "table 2" and replace with "Table 3".

Page 7, annex C, subclause C.3.2

Delete the words "table 2" and replace with "Table 3".

Page 8, annex D, subclause D.3.2

Delete the words "table 3" and replace with "Table 4".

Page 9

After annex E, create a new bibliography as follows:

“Bibliography

- [1] ISO 683-13:1986 (withdrawn), *Heat-treatable steels, alloy steels and free-cutting steels — Part 13: Wrought stainless steels.*”

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