

INTERNATIONAL STANDARD

**ISO
9626**

First edition
1991-09-01

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

Page

1	Scope	1
2	Normative references	1
3	Materials	1
4	Surface finish	1
5	Cleanliness	1
6	Limits for acidity and alkalinity	1
7	Size designation	1
8	Dimensions	2
9	Stiffness	2
10	Resistance to breakage	3
11	Resistance to corrosion	3

Annexes

A	Determination of acidity or alkalinity of tubing	5
B	Method of preparation of extracts	6
C	Test method for stiffness of tubing	7
D	Test method for resistance of tubing to breakage	8
E	Test method for resistance to corrosion	8

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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*, Subcommittee 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 0,3 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.