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Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

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

ICS: 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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 2.

The main task of technical committees is to prepare International Standards. 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 document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 9626 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition, which has been technically revised.

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

Introduction

The purposes of this International Standard are to:

a) add specifications for stainless steel needle tubing for metric sizes, 0,18 mm, 0,2 mm 0,23 mm and 0,25 mm and to reflect the introduction of thinner tubing to allow greater comfort when injecting, particularly for infants and in paediatric use,

b) add wall thickness designations beyond regular- and thin-walled tubing,

c) Add minimum inside diameters for additional items where possible,

d) revise the means of specifying the steels to be used.

Guidance on transition periods for implementing the requirements of this standard is given in ISO/TR 19244 'Guidance on transition periods for standards developed by ISO/TC 84 - Devices for administration of medicinal products and catheters'.

Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods

1 Scope

ISO 9626 provides requirements and test methods for the tube manufactured for needles as component used in medical devices. Additional performance testing on the tube aspect may be required when the component is incorporated in the ready-to-use device.

This International Standard specifies the dimensions and mechanical properties of steel tubing of designated metric sizes 3,4 mm (G10) to 0,18 mm (G34).

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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 11608-1:2012, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

ISO 15510, *Stainless steels — Chemical composition*[1)]

ISO 2958, *Road vehicles — Exterior protection for passenger cars*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply:

3.1
gauge
method of a standard dimension

Note 1 to entry: Hypodermic needles are available in a wide variety of outer diameters described by gauge numbers. Smaller gauge numbers indicate larger outer diameters. Inner diameter depends on both gauge and wall thickness.

4 Materials

Tubing shall be made by stainless steels listed in ISO 15510. The chosen materials shall be in accordance with ISO 9626 requirements and in accordance with biocompatibility requirements of ISO 10993-1. Selection of specific stainless steel material shall be made in consideration with the intended use e.g. long-term contact with drugs.

1) Under revision

5 Requirements

5.1 General

For the selection of tubing for a specific application and intended use, a risk based approach shall be applied.

5.2 Surface finish and visual appearance

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

Surface finish specifications may be different based on the final function of the medical device: in such cases the medical device manufacturer should prepare specific specifications for cleanliness.

When examined by normal or corrected vision, the needle tube shall appear straight and of regular roundness.

5.3 Cleanliness

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

Cleanliness specifications may be different based on the final function of the medical device: in such cases the medical device manufacturer should prepare specific specifications for cleanliness.

5.4 Limits for acidity and alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Annex A shall be within one unit of pH of that of the control fluid.

5.5 Size designation

Tubing shall be designated by the nominal outside diameter expressed in millimetres (i.e. the designated metric size) and by wall thickness.

EXAMPLE 0,25 mm (G31) ETW

5.6 Dimensions

The dimensions of tubing shall be as given in Tables 1 to 3.

Table 1 — Dimensions of tubing

Designated metric size (mm)	Gauge	OD_{MIN} (mm)	OD_{MAX} (mm)	Wall	ID_{MIN} (mm)
0,18	34	0,178	0,191	RW	0,064
				TW	0,091
				ETW	0,105
0,20	33	0,203	0,216	RW	0,089
				TW	0,105
				ETW	0,125
0,23	32	0,229	0,241	RW	0,089
				TW	0,105
				ETW	0,125
				UTW	0,146
0,25	31	0,254	0,267	RW	0,114
				TW	0,125
				ETW	0,146
				UTW	0,176
0,30	30	0,298	0,320	RW	0,133
				TW	0,165
				ETW	0,190
				UTW	0,240
0,33	29	0,324	0,351	RW	0,133
				TW	0,190
				ETW	0,240
				UTW	0,265
0,36	28	0,349	0,370	RW	0,133
				TW	0,190

NOTE 1 RW = Regular Wall, TW = Thin Wall, ETW = Extra Thin Wall, UTW = Ultra Thin Wall

NOTE 2 Consideration can be made to the measurement uncertainty of existing measurement equipment

Table 2 — Dimensions of tubing

Nominal OD (mm)	Gauge	OD_{MIN} (mm)	OD_{MAX} (mm)	Wall	ID_{MIN} (mm)
0,40	27	0,400	0,420	RW	0,184
				TW	0,241
0,45	26	0,440	0,470	RW	0,232
				TW	0,292
0,50	25	0,500	0,530	RW	0,232
				TW	0,292
0,55	24	0,550	0,580	RW	0,280
				TW	0,343
0,60	23	0,600	0,673	RW	0,317
				TW	0,370
				ETW	0,460
0,70	22	0,698	0,730	RW	0,390
				TW	0,440
				ETW	0,522
0,80	21	0,800	0,830	RW	0,490
				TW	0,547
				ETW	0,610
0,90	20	0,860	0,920	RW	0,560
				TW	0,635
				ETW	0,687
1,10	19	1,030	1,100	RW	0,648
				TW	0,750
				ETW	0,850

NOTE 1 RW = Regular Wall, TW = Thin Wall, ETW = Extra Thin Wall, UTW = Ultra Thin Wall

NOTE 2 Consideration can be made to the measurement uncertainty of existing measurement equipment