INTERNATIONAL STANDARD

ISO 9626

Second edition
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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 — Exigences et méthodes d'essai

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This second edition cancels and replaces the first edition (ISO 9626:1991), which has been technically revised. It also incorporates the Amendment ISO 9626:1991/Amd 1:2001.

The main changes to the previous edition of ISO 9626 introduced by this revision are the following:

a) addition of 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) addition of wall thickness designations beyond regular-walled and thin-walled tubing;

c) addition of minimum inner diameters for additional items where possible;

d) revision of the means of specifying the steels to be used;

e) revision of the table of tubing dimensions and stiffness parameters.

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

Introduction

Guidance on transition periods for implementing the requirements of this International Standard is given in ISO/TR 19244.

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

1 Scope

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.

This International Standard provides requirements and test methods for the tubes 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 (10 Gauge) to 0,18 mm (34 Gauge).

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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 15510, *Stainless steels — Chemical composition*

3 Terms and definitions

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

3.1
designated metric size
outer diameter designation of the tubing as defined in Table 1

Note 1 to entry: It is expressed in millimetres.

3.2
gauge
legacy size designation

Note 1 to entry: A particular gauge size corresponds to a designated metric size defining limits for outer diameters.

3.3
wall thickness
material thickness between the inner and outer diameter of the tube

Note 1 to entry: It is expressed as RW=Regular Wall, TW=Thin Wall, ETW= Extra Thin Wall, and UTW=Ultra Thin Wall as designated in Table 1.