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BS EN ISO 9626:2016



BSI Standards Publication

Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods (ISO 9626:2016)

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This British Standard is the UK implementation of EN ISO 9626:2016. It supersedes BS EN ISO 9626:1995 which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods (ISO 9626:2016)

Tubes d'aiguilles en acier inoxydable pour la fabrication de matériel médical - Exigences et méthodes d'essai (ISO 9626:2016)

Kanülenrohre aus nichtrostendem Stahl zur Herstellung von Medizinprodukten - Anforderungen und Prüfverfahren (ISO 9626:2016)

This European Standard was approved by CEN on 12 June 2016.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 9626:2016) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2017, and conflicting national standards shall be withdrawn at the latest by February 2017.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 9626:1995.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 9626:2016 has been approved by CEN as EN ISO 9626:2016 without any modification.

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Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Materials	2
5 Requirements	2
5.1 General.....	2
5.2 Surface finish and visual appearance.....	2
5.3 Cleanliness.....	2
5.4 Limits for acidity and alkalinity.....	2
5.5 Size designation.....	2
5.6 Dimensions.....	2
5.7 Sample size.....	5
5.8 Stiffness.....	5
5.9 Resistance to breakage.....	7
5.10 Resistance to corrosion.....	7
Annex A (normative) Methods for preparation of extracts	8
Annex B (normative) Test method for stiffness of tubing	9
Annex C (normative) Test method for resistance of tubing to breakage	11
Annex D (normative) Test method for resistance to corrosion	13
Annex E (informative) Rationale with respect to test method for stiffness of tubing	14
Bibliography	23

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.

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Introduction

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

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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](#).