SLOVENSKI STANDARD
SIST EN ISO 9626:2016

01-november-2016

Nadomešča:
SIST EN ISO 9626:2000
SIST EN ISO 9626:2000/A1:2002

Igle iz nerjavnega jekla za izdelavo medicinskih pripomočkov - Zahteve in preskusne metode (ISO 9626:2016)

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

Kanülenrohre aus nichtrostendem Stahl zur Herstellung von Medizinprodukten (ISO 9626:2016)

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

Ta slovenski standard je istoveten z: **EN ISO 9626:2016**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 9626:2016 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9626

August 2016

ICS 11.040.25

Supersedes EN ISO 9626:1995

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.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

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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.

INTERNATIONAL STANDARD

ISO 9626

Second edition
2016-08-01

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

Reference number
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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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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).

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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.