#### **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)



BS EN ISO 9626:2016

#### National foreword

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 It supersedes BS EN ISO 9626:1995 which is withdrawn.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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2016. Published by BSI Standards Limited 2016

ISBN 978 0 580 85626 6

ICS 11.040.25

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 September 2016.

Amendments/corrigenda issued since publication

Date Text affected

## 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.

CEN members are the national standards bodies of 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 United Kingdom.



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

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

© 2016 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 9626:2016 E

This is a preview. Click here to purchase the full publication.

#### **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.

Contents  Foreword  Introduction			Page
			iv
			v
1	Scope	2	1
2	Normative references		1
3	Terms and definitions		1
4	Mate	rials	2
5	Requirements		2
	5.1	General	
	5.2	Surface finish and visual appearance	2
	5.3	Cleanliness	
	5.4	Limits for acidity and alkalinity	2
	5.5	Size designation	2
	5.6	Dimensions	
	5.7	Sample size	
	5.8	Stiffness	
	5.9	Resistance to breakage	
	5.10	Resistance to corrosion	
Annex	A (no	rmative) Methods for preparation of extracts	8
Annex	B (no	rmative) Test method for stiffness of tubing	9
Annex	<b>C</b> (no	rmative) Test method for resistance of tubing to breakage	11
Annex	<b>D</b> (no	rmative) Test method for resistance to corrosion	13
Annex	E (inf	ormative) Rationale with respect to test method for stiffness of tubing	14
Biblio	graph	y	23