

SLOVENSKI STANDARD oSIST prEN ISO 9626:2026

01-januar-2026

Igle iz nerjavnega jekla za izdelavo medicinskih pripomočkov - Zahteve in preskusne metode (ISO/DIS 9626:2025)

Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods (ISO/DIS 9626:2025)

Kanülenrohre aus nichtrostendem Stahl zur Herstellung von Medizinprodukten - Anforderungen und Prüfverfahren (ISO/DIS 9626:2025)

Tubes d'aiguilles en acier inoxydable pour la fabrication de dispositifs médicaux -Exigences et méthodes d'essai (ISO/DIS 9626:2025)

Ta slovenski standard je istoveten z: prEN ISO 9626

ICS:

11.040.25 Injekcijske brizge, igle in

katetri

Syringes, needles an

catheters

oSIST prEN ISO 9626:2026

en,fr,de

oSIST prEN ISO 9626:2026

iTeh Standards (https://standards.iteh.ai) Document Preview

<u>oSIST prEN ISO 9626:2026</u>

https://standards.iteh.ai/catalog/standards/sist/7fc4ef97-92e1-4563-8a3c-0c4f3cd08465/osist-pren-iso-9626-2026



DRAFT International Standard

ISO/DIS 9626

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

ICS: 11.040.25

(https://standards.iteh.ai)

ISO/TC 84

Secretariat: DS

Voting begins on: **2025-11-24**

Voting terminates on: 2026-02-16

Document Preview

oSIST prEN ISO 9626:2026

https://standards.iteh.ai/catalog/standards/sist/7fc4ef97-92e1-4563-8a3c-0c4f3cd08465/osist-pren-iso-9626-2026

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

ISO/DIS 9626:2025(en)

iTeh Standards (https://standards.iteh.ai) Document Preview

<u>oSIST prEN ISO 9626:2026</u>

https://standards.iteh.ai/catalog/standards/sist/7fc4ef97-92e1-4563-8a3c-0c4f3cd08465/osist-pren-iso-9626-2026



COPYRIGHT PROTECTED DOCUMENT

© ISO 2025

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office CP 401 • Ch. de Blandonnet 8 CH-1214 Vernier, Geneva Phone: +41 22 749 01 11 Email: copyright@iso.org Website: www.iso.org

Published in Switzerland

ISO/DIS 9626:2025(en)

Foreword Introduction			Page
			iv
			v
1	Scope		1
2	Normative references		
3	Terms and definitions		
4	Materials		2
5	Requirements		2
	5.1	General	
	5.2	Statistics and reproducibility of test methods	2
	5.3	Surface finish and visual appearance	
	5.4	Cleanliness	
	5.5	Limits for acidity and alkalinity	
	5.6	Size designation	
	5.7	Dimensions	
	5.8	Sample size	
	5.9 5.10	Stiffness	
	5.10	Resistance to breakage	
Δnna	_	mative) Methods for preparation of extracts	
	-	mative) Test method for stiffness of tubing	
Anne	ex C (nor	mative) Test method for resistance of tubing to breakage	9
Anne	ex D (nor	mative) Test method for resistance of tubing to breakage mative) Test method for resistance to corrosion	12
Anne	ex E (info	rmative) Rationale with respect to test method for stiffness of tubing	13
		Bocument 1 10 10 W	

oSIST prEN ISO 9626:2026

https://standards.iteh.ai/catalog/standards/sist/7fc4ef97-92e1-4563-8a3c-0c4f3cd08465/osist-pren-iso-9626-2026