

# ILNAS

Institut luxembourgeois de la normalisation  
de l'accréditation, de la sécurité et qualité  
des produits et services

## ILNAS-EN ISO 11608-2:2022

### **Needle-based injection systems for medical use - Requirements and test methods - Part 2: Double-ended pen needles (ISO 11608-2:2022)**

Systemes d'injection à aiguille pour  
usage médical - Exigences et méthodes  
d'essai - Partie 2: Aiguilles à deux  
extrémités pour stylos-injecteurs (ISO

Kanülenbasierte Injektionssysteme zur  
medizinischen Verwendung -  
Anforderungen und Prüfverfahren - Teil 2:  
Kanülen mit beidseitigem Anschliff (ISO

05/2022

A decorative graphic in the bottom right corner featuring several interlocking gears in shades of blue and yellow. Overlaid on the gears is a vertical column of binary code (0s and 1s) and various mathematical symbols like plus, minus, and multiplication signs.

## National Foreword

This European Standard EN ISO 11608-2:2022 was adopted as Luxembourgish Standard ILNAS-EN ISO 11608-2:2022.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

<https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html>

### **THIS PUBLICATION IS COPYRIGHT PROTECTED**

Nothing from this publication may be reproduced or utilized in any form or by any mean - electronic, mechanical, photocopying or any other data carries without prior permission!

ILNAS-EN ISO 11608-2:2022

EUROPEAN STANDARD **EN ISO 11608-2**

NORME EUROPÉENNE

EUROPÄISCHE NORM

May 2022

ICS 11.040.25

Supersedes EN ISO 11608-2:2012

English Version

Needle-based injection systems for medical use -  
Requirements and test methods - Part 2: Double-ended  
pen needles (ISO 11608-2:2022)

Systèmes d'injection à aiguille pour usage médical -  
Exigences et méthodes d'essai - Partie 2: Aiguilles à  
deux extrémités pour stylos-injecteurs (ISO 11608-  
2:2022)

Kanülenbasierte Injektionssysteme zur medizinischen  
Verwendung - Anforderungen und Prüfverfahren - Teil  
2: Kanülen mit beidseitigem Anschliff (ISO 11608-  
2:2022)

This European Standard was approved by CEN on 2 January 2022.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, 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: Rue de la Science 23, B-1040 Brussels

<b>Contents</b>	<b>Page</b>
<b>European foreword.....</b>	<b>3</b>

## European foreword

This document (EN ISO 11608-2:2022) 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 November 2022, and conflicting national standards shall be withdrawn at the latest by November 2022.

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

This document supersedes EN ISO 11608-2:2012.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## Endorsement notice

The text of ISO 11608-2:2022 has been approved by CEN as EN ISO 11608-2:2022 without any modification.

---

---

# Needle-based injection systems for medical use — Requirements and test methods —

## Part 2: Double-ended pen needles

*Systèmes d'injection à aiguille pour usage médical — Exigences et  
méthodes d'essai —*

*Partie 2: Aiguilles à deux extrémités pour stylos-injecteurs*



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2022

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](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

	Page
Foreword.....	v
Introduction.....	vii
<b>1 Scope.....</b>	<b>1</b>
<b>2 Normative references.....</b>	<b>1</b>
<b>3 Terms and definitions.....</b>	<b>1</b>
<b>4 Symbols.....</b>	<b>3</b>
<b>5 Requirements.....</b>	<b>3</b>
5.1 Needle tube requirements.....	3
5.1.1 General.....	3
5.1.2 Needle tubing materials.....	4
5.1.3 Tubing characteristics.....	4
5.2 Double-ended pen needle requirements.....	4
5.2.1 General.....	4
5.2.2 Biocompatibility.....	4
5.2.3 Dimensions for double-ended pen needle assembly.....	4
5.2.4 Needle points.....	5
5.2.5 Freedom from defects.....	5
5.2.6 Flow rate through the needle.....	5
5.2.7 Bond between hub and needle tube.....	6
5.2.8 Dislocation of measuring point at patient end.....	7
5.2.9 Ease of assembly.....	7
5.2.10 Sterility.....	7
5.2.11 Pyrogenicity.....	8
5.3 Functional compatibility with NISs.....	8
5.3.1 General.....	8
5.3.2 Dose delivery.....	8
5.3.3 Needle removal torque.....	9
<b>6 Sampling.....</b>	<b>10</b>
<b>7 Preconditioning of needles.....</b>	<b>13</b>
7.1 Preconditioning in a dry-heat, cold storage and damp heat atmosphere.....	13
7.2 Preconditioning in a cyclical atmosphere.....	13
<b>8 Standard atmosphere and test apparatus.....</b>	<b>13</b>
8.1 Standard test atmosphere.....	13
8.2 Test gauge.....	13
8.3 Test apparatus.....	14
<b>9 Test methods.....</b>	<b>14</b>
9.1 Bond between hub and needle tube.....	14
9.2 Determination of dislocation of measuring point at patient end.....	14
9.3 Ease of assembly.....	15
9.4 Functional compatibility with NISs.....	15
9.4.1 Sample quantity requirements.....	15
9.4.2 Test procedures for testing dose delivery.....	16
9.4.3 Procedure for testing needle hub removal torque.....	17
<b>10 Packaging.....</b>	<b>17</b>
<b>11 Information supplied with the needle(s).....</b>	<b>17</b>
11.1 General.....	17
11.2 Marking.....	18
11.2.1 Marking on the unit packaging.....	18
11.2.2 Marking on the user packaging.....	19
11.3 Instructions for use.....	20