

---

**Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 1. del:  
Peresa za injiciranje - Dopnilo A1 (ISO 11608-1:2022/Amd1:2026)**

Needle-based injection systems for medical use - Requirements and test methods - Part  
1: Needle-based injection systems - Amendment 1 (ISO 11608-1:2022/Amd1:2026)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und  
Prüfverfahren - Teil 1: Kanülenbasierte Injektionssysteme - Änderung 1 (ISO 11608-  
1:2022/Amd1:2026)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai -  
Partie 1: Systèmes d'injection à aiguille - Amendement 1 (ISO 11608-  
1:2022/Amd1:2026)

**Ta slovenski standard je istoveten z: EN ISO 11608-1:2022/A1:2026**

**ICS:**

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
-----------	-------------------------------------	---------------------------------

**SIST EN ISO 11608-1:2022/A1:2026**      **en,fr,de**

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)

EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 11608-1:2022/A1**

May 2026

ICS 11.040.25

English Version

**Needle-based injection systems for medical use -  
Requirements and test methods - Part 1: Needle-based  
injection systems - Amendment 1 (ISO 11608-  
1:2022/Amd1:2026)**

Systèmes d'injection à aiguille pour usage médical -  
Exigences et méthodes d'essai - Partie 1: Systèmes  
d'injection à aiguille - Amendement 1 (ISO 11608-  
1:2022/Amd1:2026)

Kanülenbasierte Injektionssysteme zur medizinischen  
Verwendung - Anforderungen und Prüfverfahren - Teil  
1: Kanülenbasierte Injektionssysteme - Änderung 1  
(ISO 11608 1:2022/Amd 1:2026)

This amendment A1 modifies the European Standard EN ISO 11608-1:2022; it was approved by CEN on 24 April 2026.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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 amendment 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, Türkiye 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**

© 2026 CEN All rights of exploitation in any form and by any means reserved  
worldwide for CEN national Members.

Ref. No. EN ISO 11608-1:2022/A1:2026 E

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

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)

## European foreword

This document (EN ISO 11608-1:2022/A1:2026) 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 2026, and conflicting national standards shall be withdrawn at the latest by November 2026.

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.

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, Türkiye and the United Kingdom.

### Endorsement notice

The text of ISO 11608-1:2022/Amd 1:2026 has been approved by CEN as EN ISO 11608-1:2022/A1:2026 without any modification.