SLOVENSKI STANDARD
SIST EN ISO 11608-3:2022

01-julij-2022

Nadomešča:
SIST EN ISO 11608-3:2013

Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 3. del: Vsebniki in integrirane fluidne poti (ISO 11608-3:2022)

Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (ISO 11608-3:2022)

iTeh STANDARD PREVIEW

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 3: NIS-Behälter und integrierte Flüssigkeitspfade (ISO 11608-3:2022)

SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 3: Conteneurs et chemins de fluide intégrés (ISO 11608-3:2022)

Ta slovenski standard je istoveten z: **EN ISO 11608-3:2022**

ICS:

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

SIST EN ISO 11608-3:2022 **en**

2003-01.Slovenski inštitut za standardizacijo. Razmnoževanje celote ali delov tega standarda ni dovoljeno.

SIST EN ISO 11608-3:2022

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

SIST EN ISO 11608-3:2022

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11608-3

May 2022

ICS 11.040.25

Supersedes EN ISO 11608-3:2012

English Version

Needle-based injection systems for medical use - Requirements and test methods - Part 3: Containers and integrated fluid paths (ISO 11608-3:2022)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 3: Conteneurs et chemins de fluide intégrés (ISO 11608-3:2022)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 3: NIS-Behälter und integrierte Flüssigkeitspfade (ISO 11608-3:2022)

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 11608-3:2022

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

© 2022 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. EN ISO 11608-3:2022 E

SIST EN ISO 11608-3:2022

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

SIST EN ISO 11608-3:2022

European foreword

This document (EN ISO 11608-3:2022) 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 11608-3:2012.

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

Endorsement notice

SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

The text of ISO 11608-3:2022 has been approved by CEN as EN ISO 11608-3:2022 without any modification.

SIST EN ISO 11608-3:2022

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

SIST EN ISO 11608-3:2022

INTERNATIONAL STANDARD

ISO 11608-3

Third edition
2022-04

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

Part 3: Containers and integrated fluid paths

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

Partie 3: Conteneurs et chemins de fluide intégrés

SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

Reference number
ISO 11608-3:2022(E)

© ISO 2022

SIST EN ISO 11608-3:2022

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

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
Website: www.iso.org

Published in Switzerland

© ISO 2022 – All rights reserved

SIST EN ISO 11608-3:2022

Contents

Page

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/0d1040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

© ISO 2022 – All rights reserved

SIST EN ISO 11608-3:2022

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/41f0406c-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

This third edition cancels and replaces the second edition (ISO 11608-3:2012), which has been technically revised.

The main changes are as follows:

— test methods and dimensions specific to traditional pen-injector “Type A” cartridges have been removed.

A list of all parts in the ISO 11608 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

© ISO 2022 – All rights reserved

SIST EN ISO 11608-3:2022

Introduction

Developers and manufacturers of NIS are encouraged to investigate and determine if there are any other requirements relevant to the safety of their products.

Previous editions of this document focused on multi-dose pen-injector cartridges, important dimensions (e.g. inner diameter) and related attributes (e.g., disc seal eccentricity, meniscus) deemed critical for pen-injector form, fit, and function. The previous edition (i.e. ISO 11608-3:2012) included a more general discussion of "other containers" like syringes given their role in single dose NIS with automated functions (commonly referred to as auto-injectors).

iTeh STANDARD PREVIEW
(standards.iteh.ai)
SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022

© ISO 2022 – All rights reserved

SIST EN ISO 11608-3:2022

iTeh STANDARD PREVIEW
(standards.iteh.ai)

SIST EN ISO 11608-3:2022
https://standards.iteh.ai/catalog/standards/sist/411040c4-f4b8-46f0-9df2-fa40cc92f757/sist-en-iso-11608-3-2022