BS EN ISO 11608-1:2022

BSI Standards Publication

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

Part 1: Needle-based injection systems

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

National foreword

This British Standard is the UK implementation of ENISO 11608-1 and EN ISO 11608-1:2022. It is identical to ISO 11608-1:2022. It supersedes BS EN ISO 11608-1:2015, which is withdrawn.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 committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 01994 0

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 June 2022.

Amendments/corrigenda issued since publication

Date	Text affected

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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11608-1

May 2022

ICS 11.040.25

Supersedes EN ISO 11608-1:2015

English Version

Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems

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

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

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

© 2022 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 E

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

Contents

Page

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

European foreword

This document (EN ISO 11608-1:2022) 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 May 2025.

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 11608-1:2015.

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 11608-1:2022 has been approved by CEN as EN ISO 11608-1:2022 without any modification.

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

INTERNATIONAL STANDARD

ISO 11608-1

Fourth edition
2022-04

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

Part 1: Needle-based injection systems

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

Partie 1: Systèmes d'injection à aiguille

Reference number
ISO 11608-1:2022(E)

© ISO 2022

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

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

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

- All rights reserved

Contents

Page

© ISO 2022 – All rig

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

This is a preview. Click here to purchase the full publication.
- All rights reserved

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.

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).

This fourth edition cancels and replaces the third edition (ISO 11608-1:2014), which has been technically revised.

The main changes are as follows:

— relocation of content to the other parts of the ISO 11608 series, as appropriate (see Figure 1);

— added language to address the case when a platform NIS is applied for different therapeutics or users;

— clarified that the “user” referenced in this document is the patient receiving the therapeutic, and not the health care professional who prescribes the medication (see Clause 1);

— defined “bolus”, and confirmed that this document is focused on bolus (fixed dose) delivery (not basal bolus), so as to distinguish from the definition in IEC 60601-2-24 (see Clause 1);

— clarified the references to ISO 13485, ISO 14971 and IEC 62366-1 (see 5.1.2, 5.3 and 5.4, respectively) and exclude any reference to an equivalent standard;

— elimination of the term “essential performance” and defined “primary functions” - those functions for which failure would “directly” result in “new and unacceptable harm”. This is to eliminate confusion with use of the term essential performance in IEC 60601-1 (see 5.7.2, Clause 7 and Annex H). Further, there is a focus on “unacceptable harm” and not just “risk”;

— clarification of the recommendations for sample sizes for primary functions (Clause 7), simplified the number of rules from 3 to 2 (see 7.4.2.1), and updated the recommended sample sizes (see Table 3), but confirmed that different sample sizes can be chosen, if justified [see Clause 9 g)];

© ISO 2022 – All rig
This is a preview. Click here to purchase the full publication.