

**Needle-based injection systems for medical use -
Requirements and test methods - Part 2: Needles (ISO
11608-2:2012)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11608-2:2012 sisaldab Euroopa standardi EN ISO 11608-2:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11608-2:2012 consists of the English text of the European standard EN ISO 11608-2:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.04.2012.	Date of Availability of the European standard is 01.04.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 11.040.25

Standardite reprodutseerimise ja levitamise õigus kuulub Eesti Standardikeskusele

Andmete paljundamine, taastekitamine, kopeerimine, salvestamine elektroonsesse süsteemi või edastamine ükskõik millises vormis või millisel teel ilma Eesti Standardikeskuse kirjaliku loata on keelatud.

Kui Teil on küsimusi standardite autorikaitse kohta, võtke palun ühendust Eesti Standardikeskusega:
Aru 10, 10317 Tallinn, Eesti; www.evs.ee; telefon 605 5050; e-post info@evs.ee

The right to reproduce and distribute standards belongs to the Estonian Centre for Standardisation

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying, without a written permission from the Estonian Centre for Standardisation.

If you have any questions about copyright, please contact Estonian Centre for Standardisation:
Aru 10, 10317 Tallinn, Estonia; www.evs.ee; phone 605 5050; e-mail info@evs.ee

English Version

**Needle-based injection systems for medical use - Requirements
and test methods - Part 2: Needles (ISO 11608-2:2012)**

Systèmes d'injection à aiguille pour usage médical -
Exigences et méthodes d'essai - Partie 2: Aiguilles (ISO
11608-2:2012)

Nadelbasierte Injektionssysteme zur medizinischen
Verwendung - Anforderungen und Prüfverfahren - Teil 2:
Nadeln (ISO 11608-2:2012)

This European Standard was approved by CEN on 31 March 2012.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 11608-2:2012) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and intravascular 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 October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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

This document supersedes EN ISO 11608-2:2000.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 11608-2:2012 has been approved by CEN as a EN ISO 11608-2:2012 without any modification.

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Requirements	3
4.1 Materials	3
4.2 Dimensions	3
4.3 Determination of flow rate through the needle	3
4.4 Bond between hub and needle tube	3
4.5 Needle points	4
4.6 Freedom from defects	4
4.7 Lubrication	4
4.8 Dislocation of measuring point at patient end	4
4.9 Determination of functional compatibility with needle-based injection systems	4
4.10 Ease of assembly and disassembly	4
4.11 Sterility	4
5 Sampling	4
6 Pre-conditioning of needles	5
6.1 Pre-conditioning in a dry-heat atmosphere	5
6.2 Pre-conditioning in a cold-storage atmosphere	5
6.3 Pre-conditioning in a cyclical atmosphere	5
7 Standard atmosphere and apparatus for tests	6
7.1 General	6
7.2 Standard test atmosphere	6
7.3 Test gauge	6
8 Determination of dislocation of measuring point at patient end	7
9 Bond between hub and needle tube	8
10 Packaging	8
11 Test method for validating the compatibility of needles and injector systems	8
11.1 Principle	8
11.2 Apparatus and equipment	9
11.3 Sample quantity requirements	9
11.4 Procedure	9
11.5 Acceptance criteria	11
11.6 Test report	12
12 Information supplied by the manufacturer	12
12.1 General	12
12.2 Marking	12
12.3 Instructions for use	14
Annex A (normative) Determination of flow rate through needle	15
Bibliography	17

Introduction

This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with needle-based injection systems (e.g. pen injectors). These needles are often referred to as pen needles.

The devices described in this part of ISO 11608 are designed to be used with the devices described in ISO 11608-1 and ISO 11608-3.

The first edition of this part of ISO 11608 introduced the concept of interchangeability and the labelling designations “Type A” (i.e. interchangeable) and “non-Type A” for needles and container closure systems. Since its promulgation, experience has shown that the complexity of these systems makes it very difficult to ensure functional compatibility as defined in the different parts of this International Standard, particularly when products are made by different manufacturers and the design is not verified as a system. Based on this experience, it is believed that the Type A designation does not represent adequate guidance to the user in making decisions on the compatibility of needles and container closures with specific needle-based injection systems (NIS). As such, the labelling designation “Type A” has been removed.

This second edition of ISO 11608-2 addresses functional compatibility of the system through testing in accordance with Clause 11. Flow rate is introduced as a new parameter. The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer's ability to manufacture one “lot” of needles that conforms to the critical product attributes. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, for example ISO 9000.

This part of ISO 11608 does not specify requirements or test methods for freedom from biological hazards because no international agreement on the methodology and the pass/fail criteria has been reached. Guidance on biological tests relevant to double-ended needles is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such evaluation should include the effects of the sterilization process. However, national regulations might exist in some countries, which might take precedence over the guidance in ISO 10993-1.

In some countries, national regulations exist and their requirements might supersede or complement this part of ISO 11608.

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

Part 2: Needles

1 Scope

This part of ISO 11608 specifies requirements and test methods for single-use, double-ended, sterile needles for needle-based injection systems (NISs) that fulfil the specifications of ISO 11608-1.

It is not applicable to:

- needles for dental use;
- pre-filled syringe needles;
- needles pre-assembled by the manufacturer;
- needles not requiring assembly or attachment to the NIS.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7864:1993, *Sterile hypodermic needles for single use*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ISO 11608-1, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

IEC 60068-2-30:2005, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

NIS

needle-based injection system

system intended for parenteral administration by injection of medicinal products using a multi-dose or single-dose container

See Figure 1.