Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO 11608-5:2022)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11608-5:2023 sisaldab Euroopa standardi EN ISO 11608-5:2023 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11608-5:2023 consists of the English text of the European standard EN ISO 11608-5:2023.
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 and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.03.2023.	Date of Availability of the European standard is 22.03.2023.
Standard on kättesaadav Eesti Standardimis-ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

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

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11608-5

March 2023

ICS 11.040.25

Supersedes EN ISO 11608-5:2012

English Version

Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO 11608-5:2022)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 5: Fonctions automatisées (ISO 11608-5:2022)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 5: Automatisierte Funktionen (ISO 11608-5:2022)

This European Standard was approved by CEN on 10 March 2023.

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, 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

Ref. No. EN ISO 11608-5:2023 E

European foreword

The text of ISO 11608-5:2022 has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and catheters" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11608-5:2023 by 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 September 2023, and conflicting national standards shall be withdrawn at the latest by September 2023.

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 11608-5:2012.

Any feedback and questions on this document should be directed to the users' national standards body. 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 11608-5:2022 has been approved by CEN as EN ISO 11608-5:2023 without any modification.

Contents

Page

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*.

This second edition cancels and replaces the first edition (ISO 11608-5:2012), which has been technically revised.

The main changes are as follows:

— this document has been clarified to explain that an automated function is one which does not require user interaction after the action which initiates the function, including designating injection depth control as automated when the user does not have control over the depth to which the needle is inserted, even where needle insertion is performed manually.

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.

Introduction

This document is applicable to needle-based injection systems (NIS) with automated functions (NIS-AUTO) primarily intended to administer medicinal products to humans. In order to support device innovation and design, this document has been written in a format that describes the output of the design effort rather than prescribing the exact form of construction of the NIS-AUTO This document should be used in conjunction with ISO 11608-1.

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

Part 5: Automated functions

1 Scope

This document specifies requirements and test methods for automated functions in needle-based injection systems with automated functions (NIS-AUTO).

General requirements are provided for all automated functions. In addition, specific requirements are provided for the following automated functions:

a) medicinal product preparation (e.g. reconstitution);

b) needle preparation;

c) needle hiding;

d) priming;

e) dose setting;

f) needle insertion;

g) injection depth control;

h) injection of the medicinal product;

i) recording of device functions;

NOTE This document does not cover remote communication from the NIS-AUTO (pertains to wired and wireless communication transfer from the NIS auto).

j) disabling the NIS-AUTO;

k) needle retraction;

l) needle shielding;

m) needle removal.

All references to "function" in this document are by definition construed as automated functions (see 3.2). This document does not apply to functions that are performed manually by the user.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 11608-1:2022, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

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

ISO 23908:2011, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11608-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
actuation
user action that initiates an automated function

EXAMPLE *Needle insertion* (3.13). Pressing the *needle-based injection system with automated function* (3.18) against the injection site.

3.2
automated function
function that does not require user interaction after *actuation* (3.1)

Note 1 to entry: Dose counting.

3.3
disabling
function that changes the state of the *needle-based injection system with automated function* (*NIS-AUTO*) (3.18) such that it is not able to be refilled, reloaded, reset, or reactivated for dose delivery, which will allow the *NIS-AUTO* to perform any subsequent injections (including single-dose and the last dose of multi-dose NIS-AUTOs)

3.4
dose setting
function that sets the dose to be delivered

3.5
injection depth control
function or feature that controls the *needle extension* (3.11) such that the medicinal product is delivered at the *intended injection depth* (3.8)

3.6
injection of medicinal product
function that delivers the dose

3.7
injection time
time from initiation to completion of the *injection of medicinal product* (3.6) as described in the instructions for use

Note 1 to entry: The injection time that might be indicated in the instructions for use (IFU, sometime called hold time) can be the same or greater than the measured injection time, based on use risk approach.

Note 2 to entry: There can be a delay from actuation to initiation of injection that might be indicated in the IFU which might be measured and verified separately as determined by risk approach.