



**SLOVENSKI STANDARD**  
**oSIST prEN ISO 11608-5:2020**  
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**Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 5. del: Avtomatizirane funkcije (ISO/DIS 11608-5:2020)**

Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO/DIS 11608-5:2020)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 5: Automatisierte Funktionen (ISO/DIS 11608-5:2020)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 5: Fonctions automatisées (ISO/DIS 11608-5:2020)

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**ICS:**

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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## Needle-based injection systems for medical use — Requirements and test methods —

### Part 5: Automated functions

*Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —  
Partie 5: Fonctions automatisées*

ICS: 11.040.25

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## ISO/DIS 11608-5:2020(E)

### 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](http://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](http://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 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 the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

This document was prepared by 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.

Information about the revision history of the ISO 11608 series can be found in ISO 11608-1:20##.

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](http://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. Because of the anticipated variation in the designs of NIS-AUTOs, it tends to specify the results of the design effort instead of the physical and construction requirements used as the basis for NIS-AUTO design, so that innovation in achieving the intended purposes is not unnecessarily restricted. As such, this document intends to address basic elements regarding the safety and performance of NIS-AUTOs.

Despite certain advantages for intentional interchangeability for containers designed for different auto-injection systems, as well as the potential risks of inadvertent interchangeability, this document avoids setting forth design specifications for the uniform size, shape and interface of such containers. It is left for future initiatives to build upon the specifications in this document.

ISO 11608-1 is the umbrella document of the ISO 11608 series. All other parts, including this document, are to be used in conjunction with ISO 11608-1.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

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# 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 needle-based injection systems with automated functions (NIS-AUTO), including but not limited to:

- 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;
- j) disabling the NIS-AUTO;
- k) needle retraction;
- l) needle shielding;
- m) needle removal.

This document does not cover remote communication from the NIS-AUTO.

Automated features not included in the list above shall be specified and tested in accordance with the principles of this document.

All references to "function" in this document are by definition to be construed as automated functions (see 3.2). This document does not apply to these functions if they 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<sup>1)</sup>, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

1) To be published (revises ISO 11608-1:2012). Stage at time of publication: ISO/DIS 11608-1:2020.

## ISO/DIS 11608-5:2020(E)

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 terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

#### 3.1 actuation

action which initiates a NIS-AUTO function (e.g. *needle insertion* (3.14)), carried out by the NIS-AUTO user (or by another *automated function* (3.2))

EXAMPLE Pressing the *NIS-AUTO* (3.9) against the injection site.

#### 3.2 automated function

function which does not require user interaction after *actuation* (3.1)

Note 1 to entry: A dose counter is considered an automated function if it changes its state without any user interaction.

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#### 3.3 disabling

function that changes the state of the *NIS-AUTO* (3.9) such that it is not able to be refilled, reloaded, reset, or reactivated for dose delivery, which will allow the *NIS-AUTO* (3.9) to perform any subsequent injections (including single-dose and the last dose of multi-dose systems)

#### 3.4 dose setting (and memory)

function which sets the dose to be delivered (dose setting) and/or displays the previously set dose (memory)

#### 3.5 injection of medicinal product

function which delivers the dose

#### 3.6 injection time

time from *actuation* (3.1) to completion of the *injection of medicinal product* (3.5) as described in the IFU

#### 3.7 intended injection depth

range of distance from the skin surface to the point at which the medicinal product is intended to be delivered

Note 1 to entry: See Figures in [Annex C](#).

#### 3.8 medicinal product preparation

function which prepares the medicinal product for administration (e.g. reconstitution)

**3.9****needle-based injection system with automated function****NIS-AUTO**

injection system that delivers a medicinal product through a needle wherein one or a series of functions are initiated by an action of the user and controlled automatically by the injection system

Note 1 to entry: Accessories that perform automatic functions in combination with manual injection NIS-AUTOs are regarded as NIS-AUTO.

**3.10****needle cover**

cover provided over a needle in order to protect the needle from damage and users from injury prior to use

Note 1 to entry: A needle cover alone is not a sharps injury protection feature unless it complies with ISO 23908.

**3.11****injection depth control**

function which controls the *needle extension* (3.12) such that the medicinal product is delivered at the *intended injection depth* (3.7)

**3.12****needle extension**

axial distance from the patient end of the needle tip to the nearest part of the NIS-AUTO body (defining the point of contact with the patient adjacent to the injection site)

**3.13****needle hiding**

function which intentionally obscures the needle from the user's sight either before, during or after the injection cycle

Note 1 to entry: The **needle hiding function only has a visual requirement. It is not subject to any physical or dimensional requirements intended to restrict access to the needle. It does not imply any increased level of safety from needle stick injuries.**

**3.14****needle insertion**

function which inserts the needle into the injection site to the *intended injection depth* (3.7) prior to the injection of the medicinal product

**3.15****needle preparation**

function which prepares the needle for use (e.g. needle attachment, removal of *needle cover* (3.10), etc.)

Note 1 to entry: The needle preparation function may be a feature of the design and not a mechanical action. For example, a NIS cap may contain features that interact with the *needle cover* (3.10) and when the NIS cap is removed, the *needle cover* (3.10) is automatically removed.

**3.16****needle removal**

function which disconnects the needle from the NIS-AUTO fluid path

**3.17****needle retraction**

function which removes the needle from the target tissue to a predefined position inside the *NIS-AUTO* (3.9)