Nõelinfusiooni süsteemid meditsiiniliseks kasutamiseks. Nõuded ja katsemeetodid. Osa 5: Automatiseeritud funktsioonid

Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO 11608-5:2012)

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11608-5:2012 sisaldab Euroopa standardi EN ISO 11608-5:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11608-5:2012 consists of the English text of the European standard EN ISO 11608-5:2012.
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 01.10.2012.	Date of Availability of the European standard is 01.10.2012.
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.

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Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO 11608-5:2012)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 5: Fonctions automatisées (ISO 11608-5:2012)

Nadelbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 5: Automatisierte Funktionen (ISO 11608-5:2012)

This European Standard was approved by CEN on 29 September 2012.

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Foreword

This document (EN ISO 11608-5:2012) 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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, 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 11608-5:2012 has been approved by CEN as a EN ISO 11608-5:2012 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EC Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clauses 4.1 to 4.3, all parts	1	Clause 10, all parts of ISO 11608-1 addresses pre-conditioning
Clauses 4.1 to 4.4, all parts	2	Clause 10, all parts of ISO 11608-1 addresses pre-conditioning
Clauses 4.1 to 4.3, 5, 6, all parts	3	All clauses of ISO 11608-1 are applicable
NA	4	
NA	5	
Clause 4.1 parts E and G, clause 4.3 all parts	6	
Clauses 4.2.2 and 5.1.1	7	Only 7.3 is addressed
Clause 4.1 parts D	8	Only 8.3 is addressed
Clauses 4.1 to 4.4, all parts	9	9.3 is not addressed Clause 10, all parts of ISO 11608-1 addresses pre-conditioning
Clauses 4.2.5, 4.3.3.3, 4.3.5.1, 5.1.4, 5.1.7, 5.1.8.1 and 5.2	10	All clauses of ISO 11608-1 are applicable
NA	11	
NA	12	
Clause 7	13	13.5 is not addressed Clause 5.4, part D and Q and Clause 13, all parts of ISO 11608-1 address ER 13

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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Introduction

This part of ISO 11608 is applicable to needle-based injection systems with automated functions (NIS-AUTO), primarily intended to administer medicinal products to humans. Because of the anticipated variation in the designs of NIS-AUTOs, this part of ISO 11608 is promulgated more as a “horizontal” than a “vertical” standard. Thus, 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.

This part of ISO 11608 intentionally avoids addressing more than the most basic elements regarding the safety and performance of NIS-AUTOs in humans. Any intended labelling of such NIS-AUTOs indicating their use to deliver medicinal products into the body or into specified tissue strata thereof (e.g. intramuscular, subcutaneous or intradermal), or for the administration of specific pharmaceutical drugs or vaccines, falls under the authority of national governments or supranational agencies regulating the manufacture and marketing of medical NIS-AUTOs and pharmaceutical products.

This part of ISO 11608 is expected to be supplemented by additional requirements and might occasionally be superseded by such regulatory authorities. Despite certain advantages for intentional interchangeability for containers designed for different auto-injection systems, as well as the potential risks of inadvertent interchangeability, this part of ISO 11608 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 part of ISO 11608.

The sampling plans for inspection selected for this part of ISO 11608 are intended to verify the design, at a high confidence level. The sampling plan does not replace more general manufacturing quality systems, including lot release, which are addressed in standards on quality management systems, for example the ISO 9000 series or ISO 13485.

All references to “function” in this part of ISO 11608 are by definition to be construed as automated functions (see 3.4). This part of ISO 11608 does not apply to these functions if they are performed manually by the user.

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

Part 5: Automated functions

1 Scope

This part of ISO 11608 specifies requirements and test methods for the automated functions of needle-based injection systems with automated functions (NIS-AUTO), for the administration of medicinal products in humans, including but not limited to:

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

b) needle preparation;

c) air removal;

d) priming;

e) dose setting;

f) actuation;

g) needle insertion;

h) injection of the medicinal product;

i) disabling the NIS-AUTO;

j) needle retraction;

k) needle shielding;

l) needle hiding;

m) sharps injury protection;

n) needle removal.

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

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*

3 Terms and definitions

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

3.1
accessory
article or supplementary part used for convenience or safety in conjunction with a NIS-AUTO

EXAMPLES Magnifying lens to aid reading of dose setting, grip enhancer, dose counter of a NIS-AUTO.

3.2
actuation
action which initiates a NIS-AUTO function (e.g. needle insertion), triggered by the actions of the NIS-AUTO user (or by another automated function)

EXAMPLE Pressing the NIS-AUTO against the injection site.

3.3
air removal
action to remove air from the container and/or needle of the NIS-AUTO

3.4
automated function
function which does not require user initiation after actuation

NOTE A dose counter is considered an automated function if it is initiated by, for example, an automated needle retraction step, and therefore changes its state without any user interference.

3.5
injection
delivery of the dose to the intended injection depth

3.6
intended injection depth
range of injection depth to which the drug is intended to be delivered

See Figure 1.

3.7
needle-based injection system with automated functions
NIS-AUTO
injection system that delivers a medication 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 Accessories that perform automatic functions in combination with manual injection NIS-AUTOs are regarded as NIS-AUTO.

3.8
needle cover
cover provided over a needle in order to protect the needle from damage and users from injury prior to use of the needle

3.9
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)

3.10
needle hiding
function which obscures the needle from the user's sight either before, during or after the injection cycle

NOTE The needle hiding function only has a visual requirement designed to reduce patient trauma in case of needle phobia. 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.

3.11
insertion of needle
function which inserts the needle into the patient's skin to the intended injection depth prior to the injection of the medicinal product

3.12
needle shielding
function which covers the exposed needle before and/or after the injection cycle to reduce the likelihood of direct contact with the needle

NOTE 1 Needle shielding can reduce the risk of damage and contamination of the needle before use and can cover the needle after use.

NOTE 2 Needle shielding does not meet the requirements of a sharps injury protection feature unless it complies with ISO 23908.

3.13
priming
function that makes the dosing mechanism of the NIS-AUTO ready for actuation

3.14
retraction of needle
function which removes the needle from the target tissue to a predefined minimum needle point position inside the NIS-AUTO

3.15
risk assessment
RA
overall process comprising a risk analysis (estimation) and a risk evaluation

NOTE Adapted from ISO 14971:2007, definition 2.18.

3.16
sharps injury protection feature
function that prevents accidental sharps injury

NOTE The NIS-AUTO might provide an active or passive automated function (definitions of active and passive safety features are given in ISO 23908), distinct from needle shielding or hiding, which is designed to minimize the risks of accidental sharps injury. The NIS-AUTO cannot claim to have sharps injury protection unless it meets the requirements of ISO 23908.

3.17
target tissue
location in the body into which the medicinal product is delivered and that defines the route of administration

NOTE Parts of the body for this part of ISO 11608 can include the dermis, subcutaneous tissue and muscle.

4 Requirements

4.1 General requirements

a) The NIS-AUTO shall be designed to avoid unintended actuation.

b) The NIS-AUTO shall perform its intended automated functions when tested following pre-conditioning (including free fall) in accordance with ISO 11608-1.

EXAMPLE A NIS-AUTO that is dropped on a surface in accordance with free fall testing as described in ISO 11608-1 and that fails to perform any automated function as described in the instructions for use is deemed to have failed.

c) Completion of an automated function shall be apparent by visual and either tactile or audible means, or both, unless otherwise specified in any subclause of this part of ISO 11608, even if the sequence of operations for the NIS-AUTO consists of only one action. An automated function can be a sequence; if so, completion of the entire sequence shall be apparent to the user.

d) The NIS-AUTO shall not compromise container (drug product quality, consistency, etc.) and/or needle sterility. Devices designed to deliver more than one dose shall have an intermediate preparation step prior to delivery of each dose.

e) Where requirements do not specify forces for actuation of the automated feature/function, the appropriate force shall be determined by using a risk-based approach (consistent with ISO 14971) supported by simulated user studies that mimic actual clinical use.

NOTE The study design should be based on statistical considerations and should have clear acceptance criteria. Guidance on conducting simulated user studies can be found in IEC 62366.

f) Users shall be able to clearly distinguish between a NIS-AUTO that is unused, in use or disabled (or requiring another “setup” step before it can be used again). The NIS-AUTO shall provide visual feedback indicating clearly the state of the NIS-AUTO (i.e. unused, ready for use or disabled).

g) Manufacturers shall define the injection depth determined by the target tissue through clinical evaluation. Design verification shall demonstrate that the device is capable of delivering each dose of the medicinal product to the target tissue.

h) Where requirements in this part of ISO 11608 provide a test method without acceptance criteria, the manufacturer shall establish a specification and acceptance criteria for the automated feature/function appropriate to the intended use of the device using a risk-based approach (consistent with ISO 14971 and IEC 62366).

4.2 Preparation

4.2.1 General

The NIS-AUTO shall be designed to ensure that all preparation steps involving the NIS-AUTO are completed in the intended order or designed such that, if preparation steps are done out of sequence, continued safe and effective use of the NIS-AUTO is possible.

The NIS-AUTO shall indicate to the user that the preparation procedure has been completed. This shall be apparent to the user at least by visible means.

4.2.2 Drug product preparation (e.g. reconstitution)

Automated drug preparation shall not have an adverse impact on the drug product. Once preparation is complete, the contents of the container shall be visible to confirm the medicinal product has been properly prepared in accordance with the instructions for use, unless visibility adversely affects the drug product and/or therapy (see rationale in Annex A).

4.2.3 Needle preparation

The needle shall not be damaged by the automated feature (needle attachment, removal of needle cover, etc.). The automated needle preparation function shall not adversely affect the intended safety and performance of the NIS-AUTO. If any portion of the needle preparation (needle attachment, removal of needle cover, etc.) is automated, the NIS-AUTO shall not increase the potential of coring of any elastomeric components.

4.2.4 Air removal and/or priming

If the NIS-AUTO includes automated air removal and/or priming, the system shall still be able to deliver the pre-defined dose after the action is completed.

NOTE Air removal and priming can be combined into one step.

4.2.5 Dose setting

In the case of a variable dose NIS-AUTO, if designed to automatically set a dose, it shall indicate the set dose to the user by at least visual means and allow a means to adjust the set dose as appropriate.

4.3 Injection

4.3.1 Needle hiding

Needle hiding shall not interfere at any time with the NIS-AUTO intended function. If hiding the needle is required before, during or after injection, the needle shall not be visible to the user when tested in accordance with 5.1.11.1.

NOTE Post-injection needle hiding is not considered to be sharps injury protection.

4.3.2 Actuation of injection

A minimum of two manual actions shall be required in order to use the system, i.e. from locked to unlocked state/ready for injection, then press to actuate.

A multi-dose/use injection system with automated functions, once actuated, shall not allow an additional actuation without a separate and distinct action prior to a subsequent actuation.

4.3.3 Needle insertion and extension

4.3.3.1 Insertion distance

Automated needle insertion shall extend the needle tip to the specified position. This shall be confirmed through measurement of the needle extension in accordance with the methods in 5.1.7.

The manufacturer shall demonstrate that the required needle extension results in needle penetration consistent with the intended use.

The minimum force against the skin required to actuate the NIS-AUTO to achieve adequate needle insertion shall be determined in order to ensure complete penetration to the intended injection depth.

An adjustment to the needle extension specification may be required for those NIS-AUTOs that, when pressed against the skin, cause skin doming (see Figure 1). Any adjustment to this specification shall be determined by the manufacturer’s risk assessment.