SLOVENSKI STANDARD
SIST EN ISO 11608-4:2022

01-julij-2022

Nadomešča:
SIST EN ISO 11608-4:2008

Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 4. del: Peresa za injiciranje z elektronskimi elementi (ISO 11608-4:2022)

Needle-based injection systems for medical use - Requirements and test methods - Part 4: Needle-based injection systems containing electronics (ISO 11608-4:2022)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 4: Kanülenbasierte Injektionssysteme, die elektronische Bauteile enthalten (ISO 11608-4:2022)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 4: Systèmes d'injection à aiguille contenant de l'électronique (ISO 11608-4:2022)

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ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

SIST EN ISO 11608-4:2022 **en**

EUROPEAN STANDARD

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English Version

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Contents

Page

European foreword

This document (EN ISO 11608-4:2022) 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of an identical text or by endorsement, at the latest by November 2022, and conflicting national standards shall be withdrawn at the latest by November 2022.

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 11608-4:2007.

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.

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Endorsement notice

The text of ISO 11608-4:2022 has been approved by CEN as EN ISO 11608-4:2022 without any modification.

INTERNATIONAL STANDARD

ISO 11608-4

Second edition
2022-04

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

Part 4: Needle-based injection systems containing electronics

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

Partie 4: Systèmes d'injection à aiguille contenant de l'électronique

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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).

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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 second edition cancels and replaces the first edition (ISO 11608-4:2006), which has been technically revised.

The main changes are as follows:

— this document has been revised in its entirety to include requirements from the IEC 60601 series that pertain to hand-held medical injectors.

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

Needle-based injection systems, including on-body delivery systems (OBDSs), containing electronics with or without software, are primarily intended to administer medicinal products to humans. Performance requirements regarding essential electrotechnical aspects have been selected with the intention not to restrict the Electronic Needle-based Injection System (NIS-E) design unnecessarily when applying the document.

The first edition of this document was limited to pen-injectors with electromechanical drive. Pen-injectors only equipped with electronics were covered in ISO 11608-1.

Materials used for construction are not specified in this document, as their selection will depend on the design, the intended use and the process of manufacture used by individual manufacturers.

There are other international and national standards and guidance publications and, in some countries, national regulations that are applicable to medical devices and pharmaceuticals. This document is applicable to NIS-E and specifies relevant aspects of IEC 60601-1:2005+AMD1:2012+AMD2:2020, IEC 60601-1-2:2014+AMD1:2020 and IEC 60601-1-11:2015+AMD1:2020 for this particular device type.

This document does not specify non-electrotechnical requirements and test methods for NISs when specified by ISO 11608-1.

Developers and manufacturers of NIS-Es are encouraged to investigate and determine whether there are any other requirements relevant to the safety or marketability of their NIS-Es. For example, this document should be used in conjunction with IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11. A risk-based approach is expected to be applied during the design, development, and manufacture of the product. Given the specific medicinal product intended use and environment, this might result in product-specific requirements and test methods that differ from what is outlined in this document.

This document is intended to be used for type testing (testing of the development result) of NIS-E. It is not intended to be used for batch release testing.

This document introduces the notion of Type X NIS-E and Type Y NIS-E. Type X NIS-E is a device type without any physical cabled connection to other devices. Type Y NIS-E has such connections. The electrical requirements in this document for Type X NIS-E is a subset of the requirements for Type Y NIS-E.

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

Part 4: Needle-based injection systems containing electronics

1 Scope

This document specifies requirements and test methods for needle-based injection systems (NISs) containing electronics with or without software (NIS-Es).

The needle-based injection system containing electronics can be single use or reusable and can be operated with or without electrical/conductive connections to other devices. The system is intended to deliver medication to a patient by self-administration or by administration by one other operator (e.g. caregiver or health care provider).

This document applies to electronic accessories that are intended to be physically connected to a NIS or NIS-E according to the NIS/NIS-E intended use.

This document also applies to electronic accessories that are intended to have electrical/conductive connections to a NIS or NIS-E according to the NIS/NIS-E intended use.

This document does not specify requirements for software in programmable NIS-E.

NOTE IEC 60601-1:2005+AMD1:2012+AMD2:2020, Clause 14 addresses software life cycle processes.

This document does not specify requirements for cybersecurity.

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.

CISPR 11, *Industrial, scientific and medical equipment – Radio-frequency disturbance characteristics – Limits and methods of measurement*

CISPR 32, *Electromagnetic compatibility of multimedia equipment — Emission requirements*

ISO 11608-1:2022, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

ISO 7137, *Aircraft — Environmental conditions and test procedures for airborne equipment*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

IEC 60086-4, *Primary batteries — Part 4: Safety of lithium batteries*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60529, *Degrees of protection provided by enclosures (IP Code)*

IEC 60601-1:2005+AMD1:2012+AMD2:2020, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2:2014+AMD1:2020, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral Standard: Electromagnetic disturbances — Requirements and tests*

IEC 60601-1-11:2015+AMD1:2020, *Medical electrical equipment — Part 1-11: General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

IEC 60721-3-7:1995+AMD1:1996, *Classification of environmental conditions — Part 3-7: Classification of groups of environmental parameters and their severities — Portable and non-stationary use*

IEC 62133-2, *Secondary cells and batteries containing alkaline or other non-acid electrolytes — Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications — Part 2: Lithium systems*

IEC 62304, *Medical device software — Software life cycle processes*

IEC 62366-1, *Medical devices — Part 1: Application of usability engineering to medical devices*

IEC 60695-11-10:2013, *Fire hazard testing — Part 11-10: Test flames — 50 W horizontal and vertical flame test methods*

IEC 60950-1:2005+AMD1:2009+AMD2:2013, *Information technology equipment — Safety — Part 1: General requirements*

IEC 60747-5-5, *Semiconductor devices — Part 5-5: Optoelectronic devices — Photocouplers*

IEC 61000-3-2, *Electromagnetic compatibility (EMC) — Part 3-2: Limits — Limits for harmonic current emissions (equipment input current ≤16 A per phase)*

IEC 61000-3-3, *Electromagnetic compatibility (EMC) - Part 3-3: Limits — Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤16 A per phase and not subject to conditional connection*

IEC 61000-4-2:2008, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test*

IEC 61000-4-3, *Electromagnetic compatibility (EMC) — Part 4-3: Testing and measurement techniques — Radiated, radio-frequency, electromagnetic field immunity test*

IEC 61000-4-4, *Electromagnetic compatibility (EMC) — Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test*

IEC 61000-4-5, *Electromagnetic compatibility (EMC) — Part 4-5: Testing and measurement techniques — Surge immunity test*

IEC 61000-4-6, *Electromagnetic compatibility (EMC) — Part 4-6: Testing and measurement techniques — Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-8, *Electromagnetic compatibility (EMC) — Part 4-8: Testing and measurement techniques — Power frequency magnetic field immunity test*

IEC 61000-4-11, *Electromagnetic compatibility (EMC) — Part 4-11: Testing and measurement techniques — Voltage dips, short interruptions and voltage variations immunity tests for equipment with input current up to 16 A per phase*

IEC 61000-4-39, *Electromagnetic compatibility (EMC) — Part 4-39: Testing and measurement techniques — Radiated fields in close proximity—– Immunity test*

IEC 60085, *Electrical insulation — Thermal evaluation and designation*

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 http://www.electropedia.org/

3.1
access cover
part of an enclosure or guard providing the possibility of access to electrical equipment parts for the purpose of adjustment, inspection, replacement or repair

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.1]

3.2
accessible part
part of electrical equipment other than an applied part that can be touched by means of the small test finger

Note 1 to entry: See also 8.3.2.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.2, modified — "test finger" changed to "small test finger", Note 1 to entry added.]

3.3
air clearance
shortest distance in air between two conductive parts

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.5, modified — "shortest path" changed to "shortest distance".]

3.4
applied part
part of *electronic needle-based injection system* (3.13) that, in *normal use* (3.28) ,necessarily comes into physical contact with the *patient* (3.32) for *electronic needle-based injection system* to perform its function

Note 1 to entry: See also 8.3.2.1 regarding the treatment of parts that do not fall within the definition of applied parts but need to be treated as applied parts as a result of applying the risk approach process.

Note 2 to entry: See also definition of the associated term *patient connection* (3.33).

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.8, modified — "ME equipment and ME system" changed to "electronic needle-based injection system", Note 1 to entry deleted, Note 2 changed to Note 1 to entry and amended, Note 3 changed to note 2 to entry and amended.]

3.5
basic insulation
insulation providing basic protection against electric shock

Note 1 to entry: This definition does not include insulation used exclusively for functional purposes.

[SOURCE: IEC 60601-1:2005+AMD1:2012+AMD2:2020, 3.9, modified — Note 1 to entry changed.]