SLOVENSKI STANDARD
oSIST prEN ISO 11608-4:2016

01-maj-2016

Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 4. del: Peresa za injiciranje z elektronskimi elementi (ISO/DIS 11608-4:2016)

Needle-based injection systems for medical use - Requirements and test methods - Part 4: Needle-based injection systems containing electronics (ISO/DIS 11608-4:2016)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 4: Kanülenbasierte Injektionssysteme, die elektronische Bauteile enthalten (ISO/DIS 11608-4:2016)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 4: Systèmes d'injection à aiguille électroniques (ISO/DIS 11608-4:2016)

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ICS:

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

oSIST prEN ISO 11608-4:2016 **en**

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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 électroniques

ICS: 11.040.25

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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. www.iso.org/directives

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The committee responsible for this document is ISO/TC 84 *Devices for administration of medicinal products and intravascular catheters*.

ISO 11608 consists of the following parts, under the general title *Needle-based injection systems for medical use — Requirements and test methods*:

— Part 1: Needle-based injection systems

— Part 2: Needles

— Part 3: Finished containers

— Part 4: Requirements and test methods for electronic and electromechanical pen-injectors

— Part 5: Automated functions

— Part 6: On-body delivery system

— Part 7: Requirements for accessibility for persons with visual impairment

Introduction

This part of ISO 11608 covers *Needle-based injection systems containing electronics* (with or without software). These injectors are primarily intended to administer medicinal products to humans. This part of ISO 11608 provides performance requirements regarding essential aspects of the design so that variations of such injectors are not unnecessarily restricted.

For historical reasons (ISO 11608-1 was published before ISO 11608-4), the first edition of this part of ISO 11608 was limited to pen-injectors with electromechanical drive systems. Pen-injectors only equipped with electronics were covered in ISO 11608-1. Given the set of additional tests that need to be performed regarding needle-based injection systems containing electronics (ENIS) regardless of what the electronics are used for, it was decided to have all types of electronics covered by this standard.

Materials to be used for construction are not specified, 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 part of the standard serves as a stand-alone document for ENIS that specifies relevant aspects of the IEC 60601 series for this particular device type. This standard does not specify particular test methods, conditions, or acceptance criteria for NIS; other parts of ISO 11608 specify these requirements. Rather, this standard serves as a guideline for those developing ENIS. If a clause from IEC 60601-1 is not listed, it can be considered not applicable to the device under consideration.

Their requirements might supersede or complement this part of ISO 11608. Developers and manufacturers of ENISs are encouraged to investigate and determine whether there are any other requirements relevant to the safety or marketability of their products.

Manufacturers are expected to follow a risk-based approach during the design, development and manufacture of the product. Given the specific medicinal product and intended use, this might result in product-specific requirements and test methods that differ from what is outlined in this part of ISO 11608.

Needle-based injection systems for medical use — Requirements and test methods — Part 4: Needle-based injection systems containing electronics

1 Scope

This part of ISO 11608 specifies reference requirements and test methods for needle-based injection systems (NIS) containing electronics (with or without software) intended to be used with needles and with replaceable or non-replaceable containers. The electronic needle based injection system (ENIS) can be single use, reusable, and/or rechargeable. It is intended to deliver medication to an end-user by self-administration or with assistance.

This part of ISO 11608 is not applicable for devices that are capable of delivering drug while connected to an external power supply.

This part of ISO 11608 is not applicable for ancillary electrical equipment such as chargers for the device.

This part of ISO 11608 is not applicable for needle-free injectors (as covered in ISO 21649).

2 Normative references

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

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

IEC 62366-1:2015 *Medical devices - Part 1: Application of usability engineering to medical devices*

3 Terms and definitions

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

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

NOTE to entry: See also 5.9.2.1.

3.3
accessory
additional part for use with equipment in order to:

– achieve the intended use,

– adapt it to some special use,

– facilitate its use,

– enhance its performance, or

– enable its functions to be integrated with those of other equipment

[IEC 60788:2004, rm-83-06 modified]

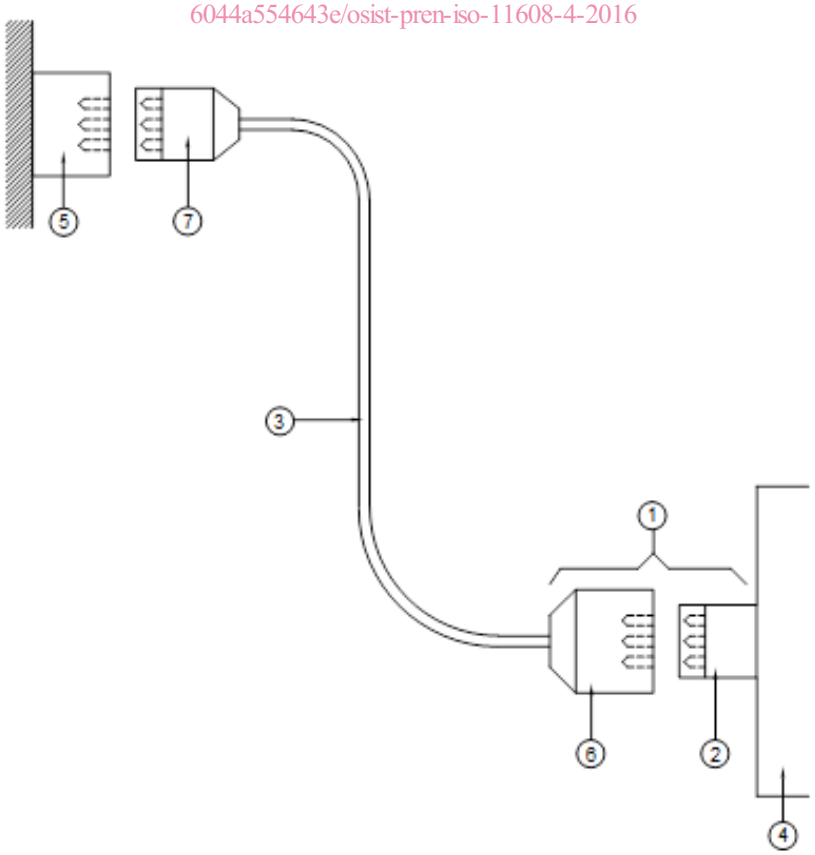
3.4
accompanying document
document accompanying ME equipment, an ME system, equipment or an accessory and containing information for the responsible organization or operator, particularly regarding basic safety and essential performance

3.5
air clearance
shortest path in air between two conductive parts

NOTE to entry: Adapted from IEC 60664-1:2007, definition 3.2.

3.6
appliance coupler
means enabling the connection of a flexible cord to electrical equipment without the use of a tool, consisting of two parts: a mains connector and an appliance inlet

NOTE to entry: See Figure 1.



Key

1 appliance coupler
2 applicance inlet
3 detachable power supply cord
4 ME equipment
5 fixed mains socket-outlet/multiple socket-outlet (MSO)
6 mains connector
7 mains plug

Figure 1 — Detachable mains connection

3.7
appliance inlet
part of an appliance coupler either integrated in or fixed to electrical equipment

NOTE to entry: See Figure 1 and Figure 2.

3.8
applied part
part of ME equipment that in normal use necessarily comes into physical contact with the patient for ME equipment or an ME system to perform its function

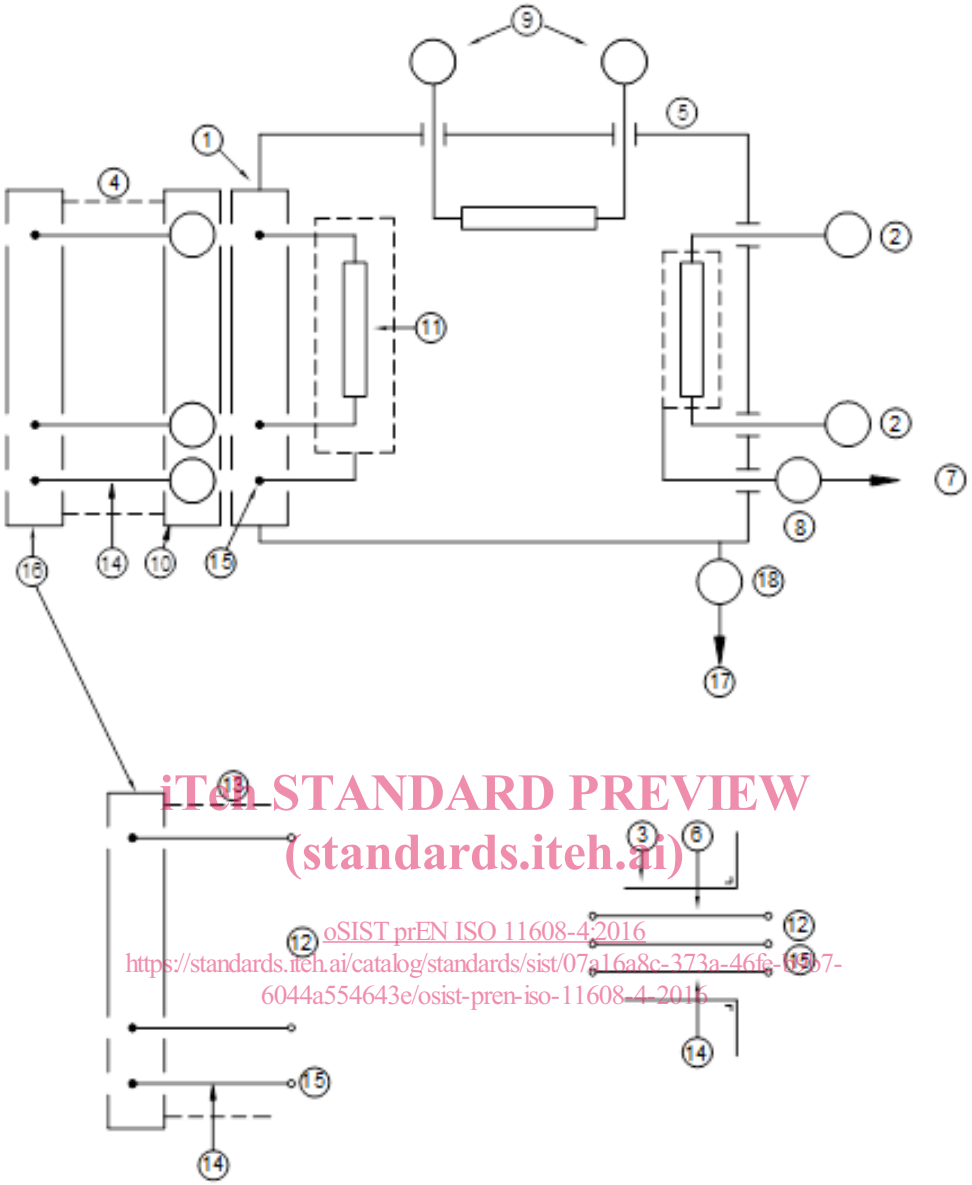
NOTE 1 to entry: See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive).

NOTE 2 to entry: See also 4.6 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 management process.

NOTE 3 to entry: See also 3.78 for the definition of the associated term patient connection.

3.9
basic insulation
insulation providing basic protection against electric shock

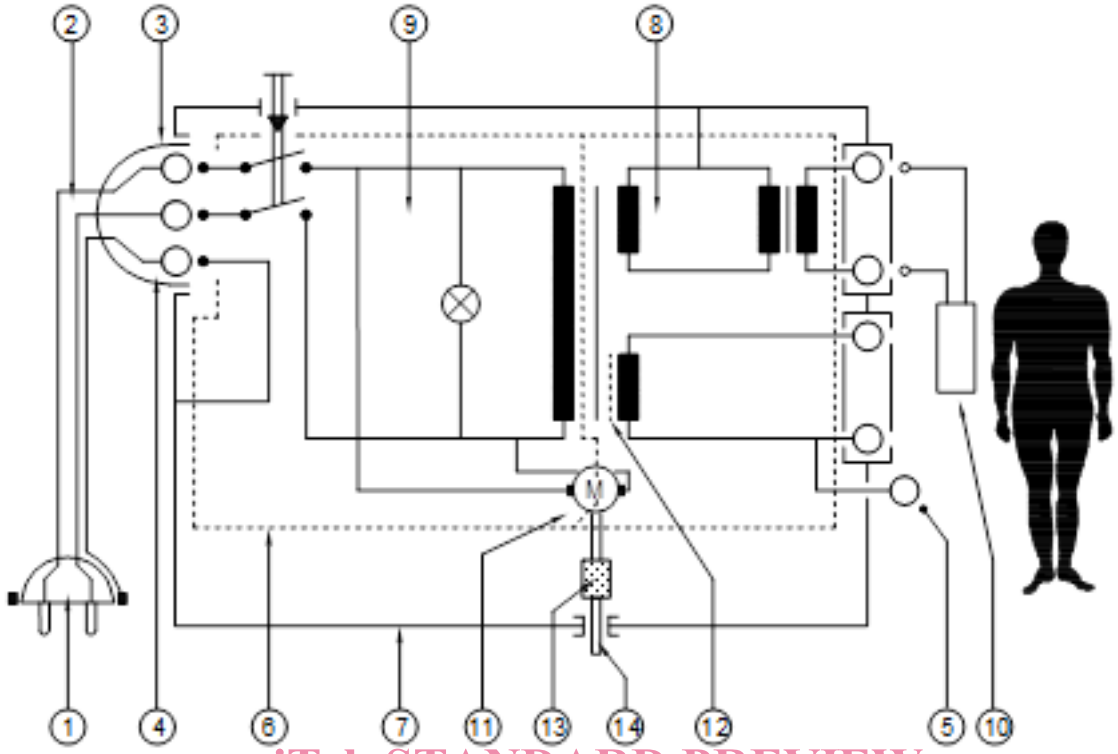
NOTE to entry: Basic insulation provides one means of protection.



Key

1 appliance inlet (see also Figure 1)
2 patient connection
3 conduit
4 detachable power supply cord
5 enclosure
6 fixed wiring
7 functional earth conductor
8 signal input/output part
9 mains conductor connector
10 mains connector
11 mains plug
12 mains terminal device
13 power supply cord
14 protective earth conductor
15 protective earth terminal
16 mains plug
17 potential equalization conductor
18 terminal for the connection of a potential equalization conductor

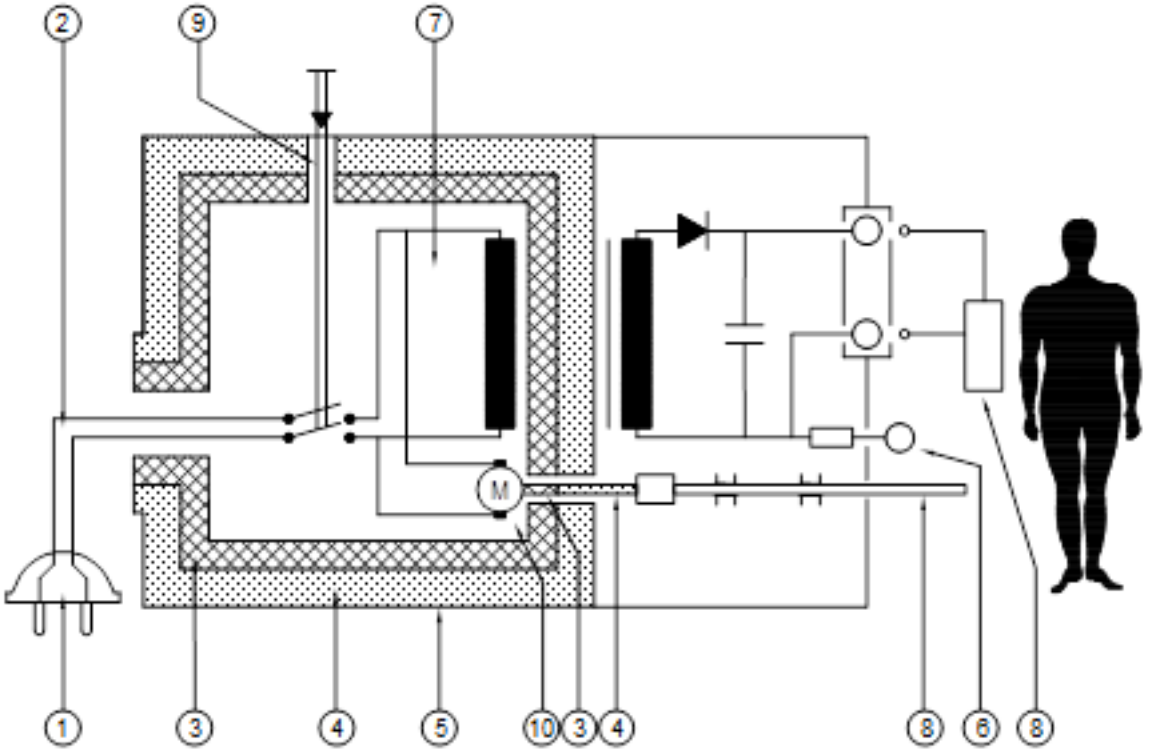
Figure 2 — Example of the defined terminals and conductors



Key

1	mains plug with protective earth contact	8	secondary circuit
2	detachable power supply cord	9	mains part
3	appliance coupler	10	applied part
4	protective earth contact and pin	11	motor
5	functional earth terminal	12	protectively earthed screen
6	basic insulation	13	supplementary insulation
7	enclosure	14	shaft that is an accessible part

Figure 3 — Example of a Class I ME equipment



Key

1	mains plug	6	functional earth terminal
2	power supply cord	7	mains part
3	basic insulation	8	applied part
4	supplementary insulation	9	reinforced insulation
5	enclosure	10	motor

Figure 4 — Example of a metal-enclosed Class II ME equipment

3.10
basic safety
freedom from unacceptable risk directly caused by physical hazards when ME equipment is used under normal condition and single fault condition

3.11
class I
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution in that means are provided for accessible parts of metal or internal parts of metal to be protectively earthed

NOTE to entry: See Figure 3.

3.12
class II
term referring to electrical equipment in which protection against electric shock does not rely on basic insulation only, but in which additional safety precautions such as double insulation or reinforced insulation are provided, there being no provision for protective earthing or reliance upon installation conditions

NOTE 1 to entry: See Figure 4.

NOTE 2 to entry: Class II equipment can be provided with a functional earth terminal or a functional earth conductor. See also 8.6.8 and 8.6.9.

3.13
clearly legible
capable of being read by a person with normal vision

NOTE to entry: See the test in 7.1.2.

3.14
continuous operation
operation in normal use for an unlimited period of time without the specified limits of temperature being exceeded

3.15
creepage distance
shortest distance along the surface of the insulating material between two conductive parts

3.16
defibrillation-proof applied part
applied part that is protected against the effects of a discharge of a cardiac defibrillator to the patient

3.17
detachable power supply cord
flexible cord intended to be connected to electrical equipment by means of a suitable appliance coupler for mains supply purposes

NOTE to entry: See Figure 1, Figure 2 and Figure 3.

3.18
direct cardiac application
use of applied part that can come in direct contact with the patient's heart

3.19
double insulation
insulation comprising both basic insulation and supplementary insulation

NOTE to entry: Double insulation provides two means of protection.

3.20
duty cycle
maximum activation (on) time followed by minimum deactivation (off) time necessary for the safe operation of the ME equipment

3.21
earth leakage current
current flowing from the mains part through or across the insulation into the protective earth conductor or a functional earthed connection according to 8.6.9

3.22
enclosure
exterior surface of electrical equipment or parts thereof

NOTE to entry: For the purpose of testing to this standard, metal foil, with specified dimensions, applied in contact with parts of the exterior surface made of material with low conductivity or made of insulating material is considered a part of the enclosure (see Figure 2, Figure 3 and Figure 4).

3.23
ENIS
[Electronic Needle-based Injection System]
injection system containing electronics intended for parenteral administration by injection of medicinal products using a needle and a multi-dose or single-dose container

3.24
essential performance

performance necessary to achieve freedom from unacceptable performance of a clinical function, other than that related to basic safety, where loss or degradation beyond the limits specified by the manufacturer results in an unacceptable risk

NOTE to entry: Essential performance is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

3.25
expected service life
maximum period of useful life as defined by the time period specified by the manufacturer during which the me equipment or me system is expected to remain safe for use (i.e. maintain basic safety and essential performance)

NOTE to entry: Maintenance can be necessary during the expected service life.

3.26
f-type isolated (floating) applied part (herein f-type applied part)
applied part in which the patient connections are isolated from other parts of the ME equipment to such a degree that no current higher than the allowable patient leakage current flows if an unintended voltage originating from an external source is connected to the patient, and thereby applied between the patient connection and earth

NOTE to entry: F-type applied parts are either type bf applied parts or type cf applied parts.

