



SLOVENSKI STANDARD SIST EN ISO 11608-3:2013

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Nadomešča:
SIST EN ISO 11608-3:2001

**Peresa za injiciranje za uporabo v medicini - Zahteve in preskusne metode - 3. del:
Končna embalaža (ISO 11608-3:2012)**

Needle-based injection systems for medical use - Requirements and test methods - Part
3: Finished containers (ISO 11608-3:2012)

Pen-Injektoren zur medizinischen Anwendung - Teil 3: Fertigkarpulen - Anforderungen
und Prüfverfahren (ISO 11608-3:2012)

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Système d'injection à aiguille pour usage médical - Exigences et méthodes d'essai -
Partie 3: Réservoirs finis (ISO 11608-3:2012)

Ta slovenski standard je istoveten z: EN ISO 11608-3:2012

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 11608-3

October 2012

ICS 11.040.25

Supersedes EN ISO 11608-3:2000

English Version

**Needle-based injection systems for medical use - Requirements
and test methods - Part 3: Finished containers (ISO 11608-
3:2012)**

Systèmes d'injection à aiguille pour usage médical -
Exigences et méthodes d'essai - Partie 3: Conteneurs prêts
à l'emploi (ISO 11608-3:2012)

Nadelbasierte Injektionssysteme zur medizinischen
Verwendung - Anforderungen und Prüfverfahren - Teil 3:
Fertigbehälter (ISO 11608-3:2012)

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

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, 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 United Kingdom.



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Foreword

This document (EN ISO 11608-3:2012) 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 supersedes EN ISO 11608-3:2000.

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.

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Endorsement notice

The text of ISO 11608-3:2012 has been approved by CEN as a EN ISO 11608-3:2012 without any modification.

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INTERNATIONAL
STANDARD

ISO
11608-3

Second edition
2012-10-01

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

**Part 3:
Finished containers**

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

Partie 3: Conteneurs prêts à l'emploi

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 11608-3 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 11608-3:2000), which has been technically revised.

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*

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ISO 11608-3:2012(E)**Introduction**

This part of ISO 11608 is applicable to containers that are provided pre-filled, or that are to be filled by the user with medicinal products intended by the manufacturer to be used with needle-based injection systems (NIS), as covered by ISO 11608.

The previous edition of this part of ISO 11608 introduced the concept of interchangeability and the labelling designation of Type A (i.e. interchangeable) and non-Type A for needles and containers.

Since its publication, experience has shown that the complexity of these systems makes it very difficult to ensure functional compatibility as defined in this International Standard, particularly when products are made by different manufacturers and the design is not verified as a system. The “Type A” designation, therefore, does not represent adequate guidance to the user in making decisions on the compatibility of needles and containers with specific NIS. As such, the labelling designation of “Type A” has been removed.

The previous edition of this part of ISO 11608 also only addressed cartridges as the drug container. This was consistent with the scope of ISO 11608 (all parts), which was previously restricted to cartridge-based injection pens. The scope of the latest revision of ISO 11608 (all parts) has been expanded beyond pen injectors and now includes all NIS, resulting in additional possibilities for compatible containers, including syringes to be used with NIS, and potentially other containers not yet defined. In order to preserve this information, this part of ISO 11608 maintains those specifications, requirements and dimensions. It is important to stress that the design requirements related to system function have been maintained as a guide to assist manufacturers during the design phase in supporting the achievement of cross-platform compatibility. However, these design requirements are an insufficient replacement for system testing of the components and, where possible, direct communication and/or quality agreements between system component manufacturers. Given the patient convenience benefits associated with cross-platform compatibility, it is helpful if manufacturers of needles, containers and NIS label their products with the specific system components that have been tested and demonstrated to be functionally compatible.

For containers other than cartridges, this part of ISO 11608 can be used as a guide to understand the parameters and design criteria to be considered in the selection and/or design of containers that will be used with NIS. It provides performance requirements regarding essential aspects so that variations of design are not unnecessarily restricted.

The sampling plans for inspection selected for this part of ISO 11608 are intended for design verification at a high confidence level. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality management systems, such as the ISO 9000 series and ISO 13485.

There are other international and national standards, guidance materials and, in some countries, national regulations that are applicable to medical devices and pharmaceuticals; their requirements might supersede or complement this part of ISO 11608. Developers and manufacturers of NIS are encouraged to investigate and determine if there are any other requirements relevant to the safety or marketability of their products.

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

Part 3: Finished containers

1 Scope

This part of ISO 11608 specifies the functional and design considerations for containers to be used with needle-based injection systems (NIS) that fulfil the specifications of ISO 11608-1. It is applicable to single and multi-dose containers (either filled by the manufacturer or by the end-user) which can be provided to the end-user integrated in the NIS or assembled with the NIS at the time of use.

This part of ISO 11608 includes specifications and test methods to describe and evaluate cartridges for use in NIS with pen needles (as defined in ISO 11608-2) and outlines design considerations for other potential containers, including syringes to be used with a NIS.

This part of ISO 11608 is not applicable to cartridges intended for dental use.

Syringes and needles that are sold separately and not intended for use in a NIS are outside the scope of this part of ISO 11608.

NOTE See ISO 7864 (needles), ISO 8537 (insulin syringes) and ISO 7886-1 (manual syringes).

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 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11040-3, *Prefilled syringes — Part 3: Seals for dental local anaesthetic cartridges*

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

ISO 11608-2, *Needle-based injection systems for medical use — Requirements and test methods — Part 2: Needles*

ISO 13926-1:2004, *Pen systems — Part 1: Glass cylinders for pen-injectors for medical use*

3 Terms and definitions

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

3.1

cap

component which attaches the disc to the cartridge

3.2

cartridge

primary container for the medicinal product