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Nålbaserade injektionssystem för medicinsk användning – Krav och provningsmetoder – Del 2: Nålar (ISO 11608-2:2012)

Needle-based injection systems for medical use – Requirements and test methods – Part 2: Needles (ISO 11608-2:2012)

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Europastandarden EN ISO 11608-2:2012 gäller som svensk standard. Detta dokument innehåller den offciella engelska versionen av EN ISO 11608-2:2012.

Denna standard ersätter SS-EN ISO 11608-2, utgåva 1.

The European Standard EN ISO 11608-2:2012 has the status of a Swedish Standard. This document contains the official version of EN ISO 11608-2:2012.

This standard supersedes the Swedish Standard SS-EN ISO 11608-2, edition 1.

Förhållandet till övriga delar under samma huvudtitel - Utdrag ur Förord i ISO 11608-2:2012/ Relations to other parts under the same general title - Extract from the Foreword of ISO 11608-2:2012

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*

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Förbrukningsmaterial inom sjukvården, SIS/TK 330.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11608-2

April 2012

ICS 11.040.25

Supersedes EN ISO 11608-2:2000

English Version

Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles (ISO 11608-2:2012)

Systèmes d'injection à aiguille pour usage médical - Exigences et méthodes d'essai - Partie 2: Aiguilles (ISO 11608-2:2012)

Nadelbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 2: Nadeln (ISO 11608-2:2012)

This European Standard was approved by CEN on 31 March 2012.

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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.

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Ref. No. EN ISO 11608-2:2012: E

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Foreword

This document (EN ISO 11608-2:2012) 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 October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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 11608-2:2000.

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Endorsement notice

The text of ISO 11608-2:2012 has been approved by CEN as a EN ISO 11608-2:2012 without any modification.

Introduction

This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with needle-based injection systems (e.g. pen injectors). These needles are often referred to as pen needles.

The devices described in this part of ISO 11608 are designed to be used with the devices described in ISO 11608-1 and ISO 11608-3.

The first edition of this part of ISO 11608 introduced the concept of interchangeability and the labelling designations “Type A” (i.e.interchangeable) and “non-Type A” for needles and container closure systems. Since its promulgation, experience has shown that the complexity of these systems makes it very difficult to ensure functional compatibility as defined in the different parts of this International Standard, particularly when products are made by different manufacturers and the design is not verified as a system. Based on this experience, it is believed that the Type A designation does not represent adequate guidance to the user in making decisions on the compatibility of needles and container closures with specific needle-based injection systems (NIS). As such, the labelling designation “Type A” has been removed.

This second edition of ISO 11608-2 addresses functional compatibility of the system through testing in accordance with Clause 11. Flow rate is introduced as a new parameter. The sampling plans for inspection selected for this part of ISO 11608 are intended to verify, at a high confidence level, the manufacturer’s ability to manufacture one “lot” of needles that conforms to the critical product attributes. The sampling plans for inspection do not replace the more general manufacturing quality systems that appear in standards on quality systems, for example ISO 9000.

This part of ISO 11608 does not specify requirements or test methods for freedom from biological hazards because no international agreement on the methodology and the pass/fail criteria has been reached. Guidance on biological tests relevant to double-ended needles is given in ISO 10993-1, and it is suggested that manufacturers take this guidance into account when evaluating products. Such evaluation should include the effects of the sterilization process. However, national regulations might exist in some countries, which might take precedence over the guidance in ISO 10993-1.

In some countries, national regulations exist and their requirements might supersede or complement this part of ISO 11608.

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

Part 2: Needles

1 Scope

This part of ISO 11608 specifies requirements and test methods for single-use, double-ended, sterile needles for needle-based injection systems (NISs) that fulfil the specifications of ISO 11608-1.

It is not applicable to:

— needles for dental use;

— pre-filled syringe needles;

— needles pre-assembled by the manufacturer;

— needles not requiring assembly or attachment to the NIS.

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 7864:1993, *Sterile hypodermic needles for single use*

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

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

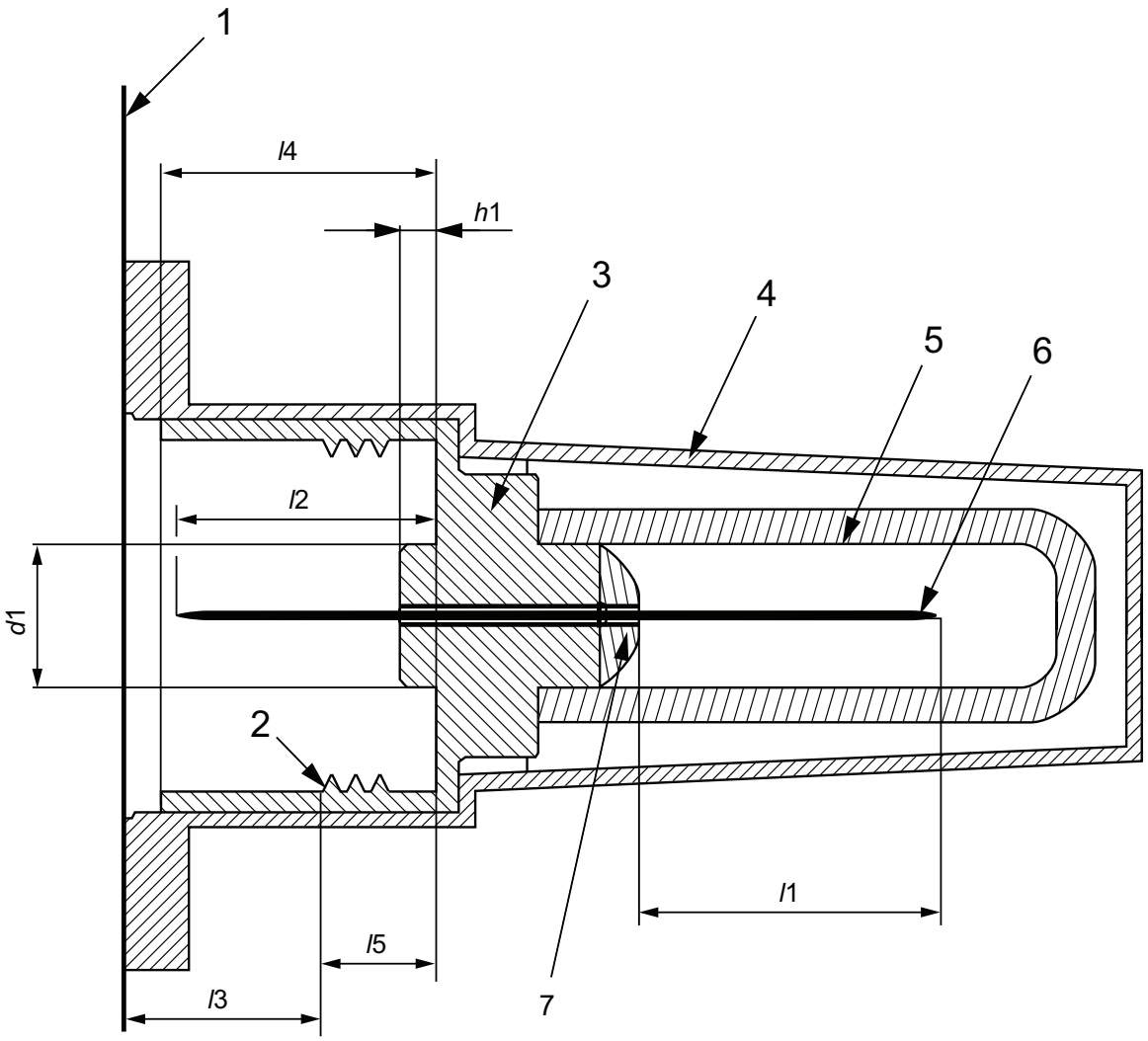
IEC 60068-2-30:2005, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

3 Terms and definitions

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

3.1
NIS
needle-based injection system
system intended for parenteral administration by injection of medicinal products using a multi-dose or single-dose container

See Figure 1.



Key

1 seal
2 means of needle assembly attachment
3 needle hub
4 needle container
5 needle shield (not required)
6 needle tube
7 jointing medium (if used)

NOTE The needle container may serve as a needle shield.

Figure 1 — Example presentation of needle assembly for a NIS

3.2
seal
removable barrier which is intended to maintain the sterility of the needle inside the needle container

3.3
unit packaging
needle container, together with the seal forming the packaging of the device, that maintains the sterility of the needle

3.4
user packaging
what is provided to the user with one or a collection of devices, in their unit packaging, of the same item and from the same manufacturing batch

4 Requirements

4.1 Materials

The needle shall be made of tubing materials specified in ISO 9626 or ISO 15510. The requirements in ISO 9626 apply.

4.2 Dimensions

4.2.1 General

The dimensions of the needle assembly attachment part shall be such that the needle fits and functions with NISs that meet the requirements specified in 11608-1.

The tubing characteristics used in needles shall meet the requirements of ISO 9626. If the tubing is not covered in that International Standard, the requirements for stiffness and breakage shall be adapted to corresponding requirements for the defined sizes.

4.2.2 Dimensions for needles

Needles shall fit the test apparatus specified in 7.3. Dimensions shall be in accordance with Table 1.

Table 1 — Dimensional requirements of needle assembly

Measurements	Dimensions mm
l_1	specified length ±1,25
l_2	5,7 to 7,0
l_3	<6,0
l_4	<7,5
l_5	<3,7
h_1	0 to 1,0
d_1	0 to 3,0

Needles may be deliberately designed not to fit the test gauge described in 7.3 and not to meet the dimensional requirements given in Table 1. In such cases, a dedicated test gauge for the specific design shall be created in order to perform the test in 4.8. In addition, the remaining requirements, other than those in 4.2.2, shall apply. In cases where the dimensional requirements of 4.2.2 are not met, the labelling shall state that the needle be used exclusively with the NIS designed for, and tested with, this needle.

4.3 Determination of flow rate through the needle

The needle shall be tested in accordance with Annex A to determine the flow rate through the needle, in millilitres per minute. In addition to complying with the labelling requirements of Clause 12, the flow rate shall be made available on request.

NOTE The flow rate parameter is not a strict requirement of Clause 12, but may be of interest for a NIS manufacturer or other party. Flow rate is an important factor in the overall NIS system performance, as is the injection force and injection time.

4.4 Bond between hub and needle tube

The union of the hub and needle tube shall not break when tested in accordance with Clause 9.