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

Part 2: Double-ended needles

ICS: 11.040.25

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Foreword

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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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For an explanation of 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 the following URL: www.iso.org/iso/foreword.html.

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

This third edition cancels and replaces the second edition (ISO 11608-2:2012), which has been technically revised.

Information about the revision history of the ISO 11608 series can be found in ISO 11608-1:20##.

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

This document 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 document are designed to be used with the devices described in ISO 11608-1 and ISO 11608-3. ISO 11608-1 is the umbrella document. All other parts, including this document, are used in conjunction with ISO 11608-1.

The first edition of this document 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.

The second edition of this document addressed functional compatibility of the system through testing in accordance with Clause 11. Flow rate was introduced as a new parameter. The sampling plans for inspection selected for this document and outlined in 11608-1 are intended to verify the design, at a high confidence level. The sampling plan does not replace the more general manufacturing quality systems, including lot release, which appear in standards on quality systems, e.g. ISO 9001 or ISO 13485.

This document 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 document.

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

Needle-based injection systems for medical use — Requirements and test methods — Part 2: Double-ended needles

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

Part 2: Double-ended needles

1 Scope

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

NOTE Needles provided by the manufacturer integrated into the fluid path or container are covered in ISO 11608-3, and hypodermic needles provided separately are covered in ISO 7864.

This document is not applicable to:

— needles for dental use;

— pre-filled syringe needles;

— needles intended for different routes of administration (e.g. intravenous, intrathecal, intraocular).

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.

ISO 9626:2016, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

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

ISO 11608-3, *Needle-based injection systems for medical use — Requirements and test methods — Part 3: NIS containers and fluid paths*

ISO 13926-2, *Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use*

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 terminological databases for use in standardization at the following addresses:

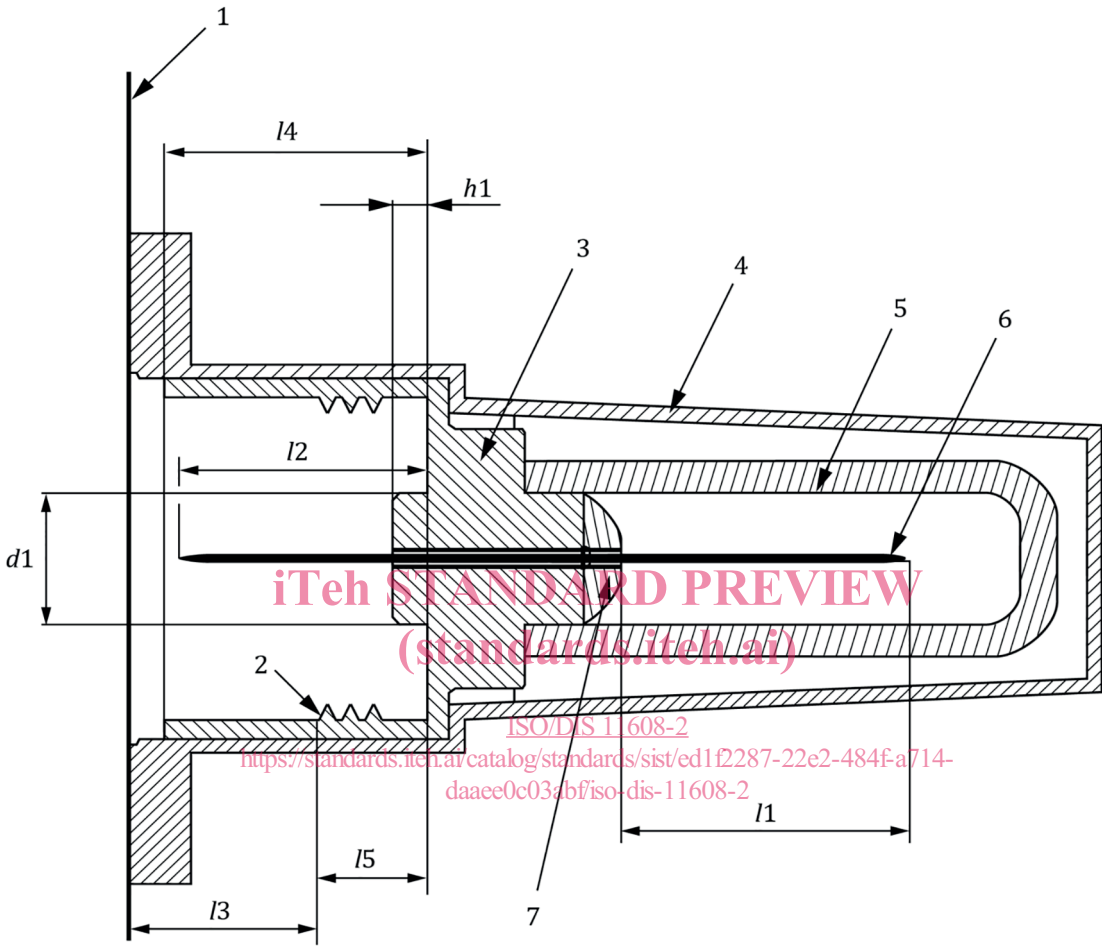
— IEC Electropedia: available at http://www.electropedia.org/

— ISO Online browsing platform: available at http://www.iso.org/obp

1) To be published (revises ISO 11608-1:2012). Stage at time of publication: ISO/DIS 11608-1:2020.

3.1
pen needle
single-use, double-ended, sterile needles with attachment system specific for needle-based injection systems (NISs)

Note 1 to entry: See Figure 1.



Key

1	*seal* (3.2)	*l*1	patient-end needle length
2	means of needle assembly attachment	*l*2	cartridge-end needle length
3	needle hub	*l*3	distance from the surface of the *seal* (3.2) to the underside of the thread
4	needle container	*l*4	depth of the needle hub
5	needle shield (if included)	*l*5	distance from the underside of the thread to the surface of the hub base
6	needle tube	*h*1	needle hub union length
7	jointing medium (if used)	*d*1	diameter of needle hub union

Figure 1 — Example presentation of pen needle assembly

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* (3.2) 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* (3.3), of the same item and from the same manufacturing batch

4 Requirements

4.1 Needle component requirements

4.1.1 General

These requirements relate to the needle component included in the pen needle device.

4.1.2 Materials

The needle shall be made of tubing materials specified in ISO 9626:2016, Clause 4.

4.1.3 Tubing characteristics

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

4.1.4 Dimensions for needle assembly

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 ISO 11608-1. 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

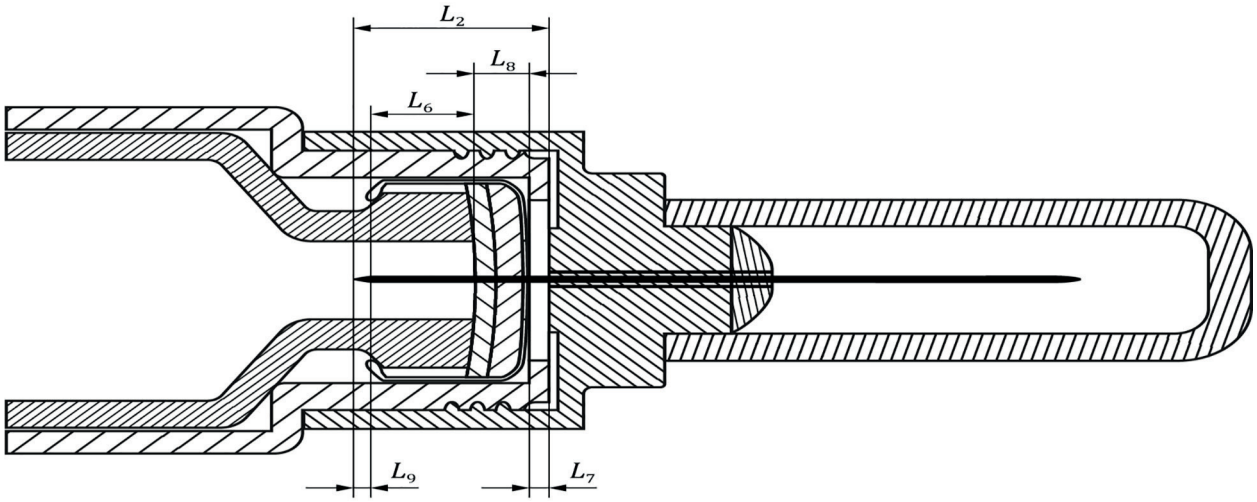
Needle manufacturers shall consider the risk of not delivering to the target tissue when setting the specifications per Table 1, e.g. for needles of less than 6 mm in length.

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 needle labelling shall list the NIS(s) and accessories for which it has been designed and tested.

4.1.5 Positioning of needle bevel inside the cartridge

When the needle is applied to the NIS with a torque of (0,08 ± 0,02) Nm the needle bevel shall be placed behind the septum (L_6 > 0 mm).

NOTE Verification of this requirement can be based on calculations of worst case (e.g. taking into account impact by tolerance, impact by deformation of the septum due to friction between needle and septum).



Key

L_2 cartridge-end needle length
L_6 gap between bevel and septum
L_7 bottom thickness of cartridge holder
L_8 thickness of septum (According to ISO 13926-2)
L_9 length of bevel cut

NOTE $L_{6,min} = L_{2,min} - \left(L_{9,max} + L_{8,max} + L_{7,max}\right)$

Figure 2 — Positioning of needle bevel inside the cartridge

4.1.6 Needle points

When visually examined by normal or corrected to normal vision under magnification of ×2,5 and illuminance of 215 ±20 lx at a reading distance of between 30 cm and 70 cm needle points shall appear sharp and free from feather edges, burrs and hooks.

NOTE The resolution of the human eye is approximately 5µm. Based on this, burrs of around 0,05 mm can be detected.

$$U = \frac{1}{1,min} = 0,82\frac{D}{\lambda}$$

where

U is resolution;

$\alpha_{1,\min}$ is angular distance;

D is circular opening of the pupil, where the light is deflected:

λ is average wavelength of the visual light.

The needle point at the cartridge end shall be designed so as to minimize coring and fragmentation when penetrating the cartridge septum. Test procedure as specified in ISO 11608-3:20##, 5.2.

4.1.7 Freedom from defects

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 215 ±20 lx at a reading distance of between 30 cm and 70 cm, the outer surface of the tubing shall be smooth and free from defects.

4.1.8 Lubrication

The needle tube shall be lubricated at both the patient end and the cartridge end. The lubricant shall not, under normal or corrected-to-normal vision (and illuminance of 215 ±20 lx at a reading distance of between 30 cm and 70 cm), be visible as droplets of fluid on the outside surface of the needle tube.

4.1.9 Cleanliness

When inspected by normal or corrected-to-normal vision without magnification under an illuminance of 300 lx to 700 lx, the surface of the needle tube (patient end and cartridge end) shall appear free from particles and extraneous matter.

When examined under 2,5× magnification, the hub socket (fluid path surface) shall appear free from particles and extraneous matter.

4.1.10 Limits for acidity or alkalinity

When determined with a laboratory pH meter and using a general purpose electrode, the pH value of an extract prepared in accordance with Annex C shall be within one unit of pH of that of the control fluid.

4.1.11 Limits for extractable metals

When tested by a recognized microanalytical method, for example by an atomic absorption method, an extract prepared in accordance with Annex C shall, when corrected for the metals content of the control fluid, contain not greater than a combined total of 5 mg/l of lead, tin, zinc and iron. The cadmium content of the extract shall, when corrected for the cadmium content of the control fluid, be lower than 0,1 mg/l.

4.1.12 Patency of lumen

As appropriate, depending on the needle size and geometry of the needle, patency of the lumen shall be determined by either:

a) a stainless steel stylet of the appropriate diameter selected from the diameters given in Table 2 shall pass through the needle;

b) the flow rate of water through the needle shall not be less than 80 % of an unprocessed needle tube of equivalent outer diameter and length having a minimum inner diameter in accordance with ISO 9626 when tested under the same pressure.

   For needles tapered inside, the patency of lumen shall be verified by flow rate measurements. The unprocessed needle tube should have minimum inner diameter at both the tip and hub corresponding to their respective designations from ISO 9626.

An example of an appropriate method to determine flow rate is given in Annex C.

It is recommended to use method b) for needles below 0,30 mm and hence no stylets are listed in Table 2 for designated metric sizes below 0,30 mm.