INTERNATIONAL STANDARD

ISO 11608-2

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Pen-injectors for medical use —

Part 2: Needles — Requirements and test methods

Stylos-injecteurs à usage médical —

Partie 2: Aiguilles — Exigences et méthodes d'essai

Reference number
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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

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 part of ISO 11608 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 11608-2 was prepared by Technical Committee ISO/TC 84, *Medical devices for injections*.

ISO 11608 consists of the following parts, under the general title *Pen-injectors for medical use*:

— *Part 1: Pen-injectors — Requirements and test methods*

— *Part 2: Needles — Requirements and test methods*

— *Part 3: Finished cartridges — Requirements and test methods*

Introduction

This part of ISO 11608 covers sterile double-ended needles intended for single use in conjunction with pen-injectors.

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

It is recognized that interchangeability of the components (pen-injector, needle and cartridge) is desirable for some medicinal products and should be avoided for other medicinal products, and that future design may change the current concepts. Therefore, ISO 11608-2 and ISO 11608-3 encourage interchangeability by establishing certain specific requirements for interchangeable needles (Type A) and interchangeable cartridges (Type A) respectively.

Performance requirements are imposed on both interchangeable (Type A) and non-interchangeable (non-Type A) needles. Additional dimensional requirements are imposed on interchangeable needles (Type A).

Information as to whether the components are interchangeable (Type A) or not should be given on the unit container.

It is desirable that non-Type A needles do not fit pen-injectors intended for Type A needles.

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, e.g. the ISO 9000 series.

This part of ISO 11608 does not specify requirements or test methods for freedom from biological hazards, because international agreement upon the methodology and the pass/fail criteria is incomplete. 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 process whereby the needles are sterilized. However, national regulations may exist in some countries, and these may take precedence over the guidance in ISO 10993-1.

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

Pen-injectors for medical use —

Part 2:
Needles — Requirements and test methods

1 Scope

This part of ISO 11608 specifies requirements and test methods for single-use, double-ended, sterile needles for pen-injectors which fulfil the specifications of ISO 11608-1.

It is not applicable to needles for dental use.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 11608. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11608 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 6009:1992, *Hypodermic needles for single use — Colour coding for identification.*

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

ISO 9626:1991, *Stainless steel needle tubing for the manufacture of medical devices.*

ISO 11608-1:2000, *Pen-injectors for medical use — Part 1: Pen-injectors — Requirements and test methods*.

IEC 60068-2-30:1980, *Environmental testing — Part 2: Test Db and guidance: Damp heat, cyclic (12 + 12-hour cycle).*

3 Terms and definitions

For the purposes of this part of ISO 11608, the following terms and definitions apply.

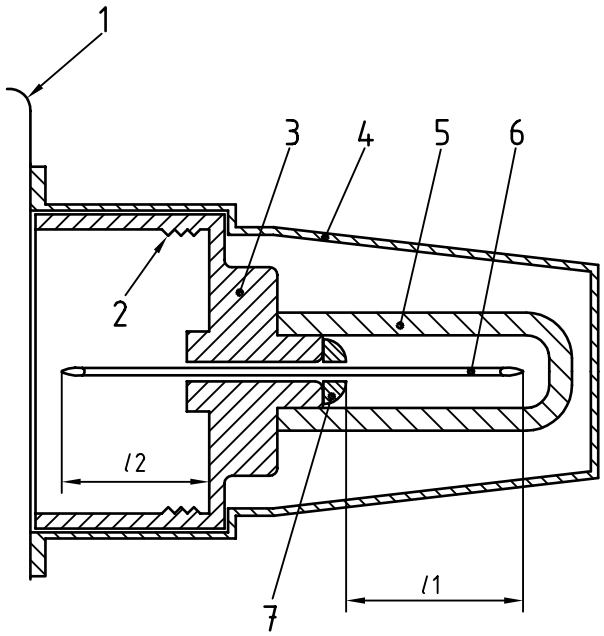
The nomenclature of some components of a needle for a pen-injector is given in Figure 1.

3.1
primary container
that part of the packaging which maintains sterility of the needle

NOTE The primary container may serve as a needle shield.

3.2
unit container
package intended for customer use

3.3
seal
removable barrier which is intended to maintain the sterility of the needle inside the primary container



Key

1 Seal
2 Means of needle assembly attachment
3 Needle hub
4 Primary container
5 Needle shield
6 Needle tube
7 Jointing medium (if used)

Figure 1 — Schematic presentation of needle assembly for pen-injectors

4 Requirements

4.1 Colour coding

If colour coding is used for designation of the diameter of the needle, the colour coding shall be in accordance with the requirements of ISO 6009.

4.2 Materials

The needle should be made of tubing materials in accordance with ISO 683-13.

4.3 Dimensions

4.3.1 General

The tubing diameters should be in accordance with the requirements given in Table 1 of ISO 9626:1991.

The dimensions of the attachment part of the needle shall be such that the needle fits and functions with pen-injectors which are in accordance with ISO 11608-1.

4.3.2 Type A needles

Type A needles shall fit the test apparatus specified in 7.2 and function with pen-injectors designated and labelled to be used with Type A needles.

The length (l_2) of the cartridge-end of the needle shall be within 3,50 mm to 7,25 mm (see Figure 1).

The tolerance on the length (l_1) of the patient-end of the needle shall be ± 1,25 mm of the length specified by the manufacturer (see Figure 1).

4.3.3 Non-Type A needles

Non-Type A needles shall fit and function with identified pen-injectors designed and labelled to be used with the particular non-Type A needle.

The length (l_2) of the cartridge-end shall ensure adequate penetration of the cartridge seal when mounted on the pen-injector for which it is intended.

The tolerance on the length (l_1) of the patient-end of the needle shall be ± 1,25 mm of the length specified by the manufacturer.

4.4 Patency of lumen

The needle tube shall have a patency such that a stylet, having a diameter equivalent to (80 ± 2) % of the inner diameter of the tube, will pass through freely.

4.5 Needle points

When examined under × 2,5 magnification, needle points shall appear sharp and free from feather edges, burrs and hooks.

The needle point at the cartridge end shall be designed so as to minimize coring and fragmentation when penetrating the cartridge septum.

4.6 Freedom from defects

The needle tube shall fulfil the requirements of 11.3 in ISO 7864:1993.

4.7 Lubrication

If the needle tube is lubricated, the lubricant shall not, under normal or corrected-to-normal vision, be visible as droplets of fluid on the outside or inside surface of the needle tube.