
**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

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).

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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

3.3

cylinder

main body of the container

3.4

deliverable volume

contents of the container which are accessible by utilizing the delivery device in accordance with the instructions for use

NOTE Deliverable volume can be less than fill volume.

3.5

disc

component which seals the end of the container opposite the plunger

3.6

initiating force

break-loose force

force required to dislodge the plunger from its resting position

3.7

label

identification of the contents of the container

3.8

particle-free water

water that has passed through 0,2 micron pore-size filter media

3.9

plunger

component which seals one end of the container and interfaces with the plunger rod of the delivery device

3.10

plunger rod

delivery device mechanism which advances the plunger to deliver the medicinal product

3.11

sustaining force

force required to maintain constant plunger velocity through the cylinder

3.12

user packaging

what is provided to the user with one or a collection of containers, in their unit packaging, of the same item and from the same manufacturing batch item, including the directions for use as appropriate

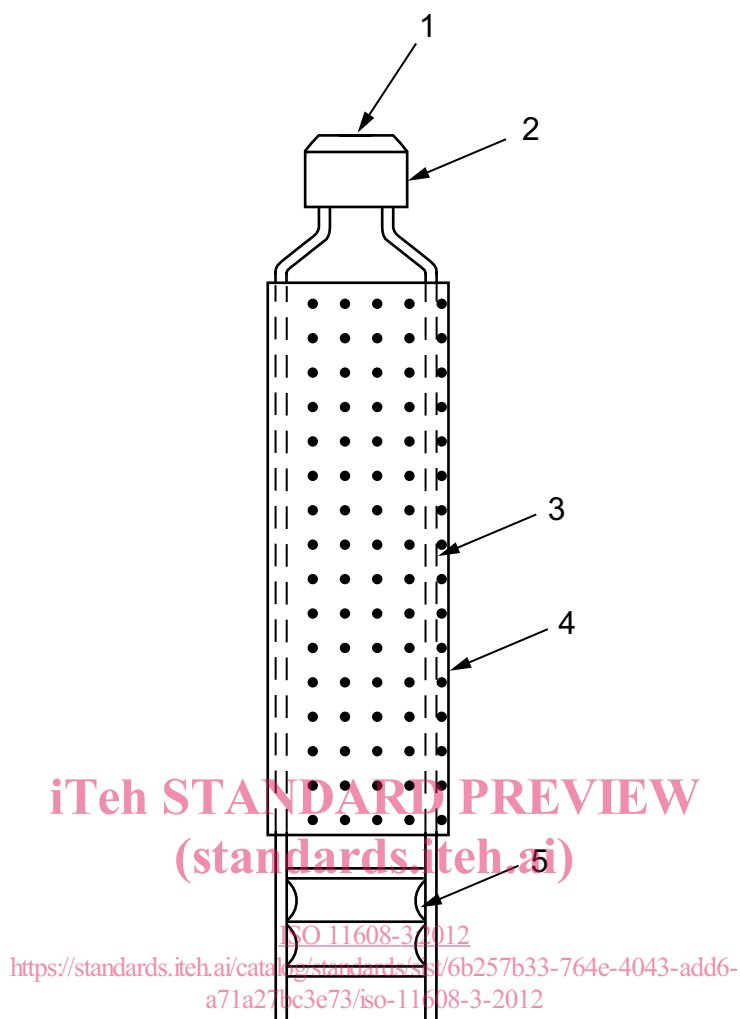
3.13

unit packaging

individual packaging of the container that maintains the sterility of the product

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Key

- 1 disc
- 2 cap
- 3 cylinder
- 4 label
- 5 plunger

Figure 1 — Finished cartridge

4 Requirements

4.1 General

These requirements apply to any container intended to be used with a NIS. When test methods and specifications are noted, they are included to assist manufacturers and suppliers in supporting the achievement of cross-platform compatibility for compatible cartridges for use in NIS.

All materials shall be compatible or resistant, or both, to the medicinal product to be injected with the NIS.

NOTE The containers are cartridge-based or syringe-based and made of plastic or glass. The cartridges are used with needles (as specified in ISO 11608-2). The syringes may have a staked-on needle, a luer, a luer lock or other special connector for needle attachment.

4.2 Freedom from leakage

4.2.1 All containers

The container shall be free from leakage when tested with the NIS in accordance with ISO 11608-1.

4.2.2 Cartridges

Cartridges shall not leak at the plunger or the disc when tested in accordance with the method given in 5.5.

4.3 Plunger force

4.3.1 All containers

The force to initiate and sustain plunger movement in the container shall not result in incomplete or inaccurate doses when tested with NIS in accordance with ISO 11608-1. Testing shall include containers that are at, or representative of, their end of shelf life.

4.3.2 Cartridges

The initiating force for cartridges shall not exceed 15 N, when tested in accordance with the method given in 5.4.

The sustaining force for cartridges shall not exceed 10 N, when tested in accordance with the method given in 5.4.

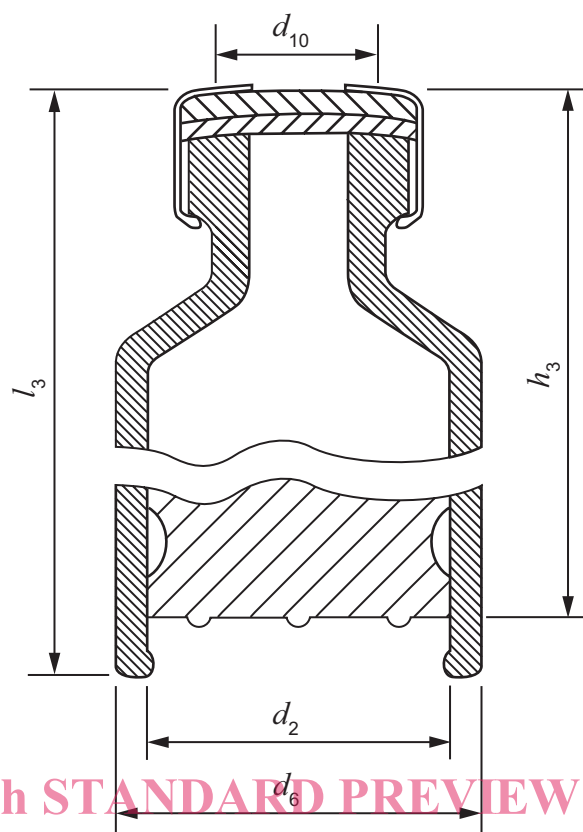
4.4 Dimensions

4.4.1 All containers

The dimensions of the container shall be such that it fits and functions correctly with identified compatible NIS fulfilling the specifications of ISO 11608-1.

4.4.2 Cartridges

For cartridges, the dimensions l_3 and h_4 shall be measured in accordance with the test method in 5.6.1 and 4.5.2, respectively. Dimensions d_6 and h_3 shall be measured in accordance with the test method in 5.6.2.



NOTE The dimensions given are the minimal dimensions that should be identified for cartridges. There may be additional relevant dimensions to be identified for a particular system.

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Figure 2 — Finished cartridge dimensions

4.5 Eccentricity

4.5.1 All containers

The allowable eccentricity of the container shall be such that it does not interfere with the fit and function of the identified compatible NIS fulfilling the specifications of ISO 11608.

4.5.2 Cartridges

For cartridges, the maximum eccentricity shall be determined in accordance with the test method in 5.6.3.

4.6 Visibility of the medicinal product — All containers

The contents of the container shall remain visible as specified in ISO 11608-1.

4.7 Meniscus — Cartridge only

For cartridges, the meniscus of the medicinal product in unpenetrated cartridges shall not extend below dimension h_4 .

4.8 Resealability — All containers

After having been penetrated as specified in 5.6.6, the penetrated septum or membrane of 20 containers shall not leak from the penetration site when the container is pressurized at a minimum force of 5 N. If the risk