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

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NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 11608-3:2012 sisaldab Euroopa standardi EN ISO 11608-3:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11608-3:2012 consists of the English text of the European standard EN ISO 11608-3:2012.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.10.2012.	Date of Availability of the European standard is 01.10.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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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)

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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of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.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.

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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.

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

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