

**Needle-based injection systems for medical use -
Requirements and test methods - Part 1: Needle-based
injection systems (ISO 11608-1:2012)**

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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English Version

**Needle-based injection systems for medical use - Requirements
and test methods - Part 1: Needle-based injection systems (ISO
11608-1:2012)**

Systèmes d'injection à aiguille pour usage médical -
Exigences et méthodes d'essai - Partie 1: Systèmes
d'injection à aiguille (ISO 11608-1:2012)

Nadelbasierte Injektionssysteme zur medizinischen
Verwendung - Anforderungen und Prüfverfahren - Teil 1:
Nadelbasierte Injektionssysteme (ISO 11608-1:2012)

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Foreword

This document (EN ISO 11608-1:2012) 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of an identical text or by endorsement, at the latest by October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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Endorsement notice

The text of ISO 11608-1:2012 has been approved by CEN as a EN ISO 11608-1:2012 without any modification.

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Introduction

This part of ISO 11608 covers needle-based injection systems (referred to as NISs) primarily intended for human use. It provides performance requirements regarding essential aspects so that variations of design are not unnecessarily restricted.

This part of ISO 11608 should be used in conjunction with the other parts of ISO 11608.

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 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. 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 containers with specific needle-based injector systems. As such, the labelling designation “Type A” has been removed. The design requirements related to system function have been maintained as a guide to assist manufacturers during the design phase, 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. Therefore, given the patient convenience benefits associated with cross-platform compatibility, manufacturers of needles, containers and needle-based injectors shall label their products with the specific system components that have been tested and demonstrated to be functionally compatible.

The sampling plans for inspection selected for this part of ISO 11608 are intended to verify the design 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 systems, for example the ISO 9000 series and ISO 13485.

Materials to be used for construction are not specified, as their selection will depend on the design, the intended use and the process of manufacture used by individual manufacturers.

There are other international and national standards and guidance publications 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 NISs are encouraged to investigate and determine whether there are any other requirements relevant to the safety or marketability of their products.

Manufacturers are expected to follow a risk-based approach during the design, development and manufacture of the product. Given the specific medicinal product and intended use, this might result in product-specific requirements and test methods that differ from what is outlined in this part of ISO 11608.

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

Part 1: Needle-based injection systems

1 Scope

This part of ISO 11608 specifies requirements and test methods for needle-based injection systems (NISs) intended to be used with needles and with replaceable or non-replaceable containers. Containers covered in this part of ISO 11608 include single- and multi-dose syringe-based and cartridge-based systems, filled either by the manufacturer or by the end-user.

Additional guidance for NISs equipped with electronic or electromechanical components and NISs equipped with automated functions is given in ISO 11608-4 and ISO 11608-5 respectively.

Needle-free injectors, and requirements relating to methods or equipment associated with end-user filling of containers, are outside the scope of this part of ISO 11608.

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 11608 (all parts), *Needle-based injection systems for medical use — Requirements and test methods*

ISO 13485:2003, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14253-1, *Geometrical Product Specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for proving conformance or non-conformance with specifications*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO/IEC Guide 98-3, *Uncertainty of measurement — Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

IEC 60068-2-6:2007, *Environmental testing — Part 2-6: Tests — Test Fc: Vibration (sinusoidal)*

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

IEC 60601-1-2:2007, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 62366, *Medical devices — Application of usability engineering to medical devices*