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

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

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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of an identical text or by endorsement, at the latest by October 2012, and conflicting national standards shall be withdrawn at the latest by October 2012.

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

Part 1: Needle-based injection systems

Systèmes d'injection à aiguille pour usage médical — Exigences et méthodes d'essai —
Partie 1: Systèmes d'injection à aiguille

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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.

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ISO 11608-1 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 11608-1:2000), 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 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*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
cap
part of the NIS intended to protect the injector and its contents

3.2
container
primary packaging that contains the medicinal product for injection (either single-compartment or multi-compartment)

3.3
dose delivery efficiency
ratio of expelled dose to fill volume

NOTE 1 Dose delivery efficiency is expressed as a percentage.

NOTE 2 Delivery efficiency can be used to evaluate dose accuracy for NISs designed to fully empty single-dose containers filled by the user.

3.4
dialling resolution
smallest possible increment to be selected between dose amounts

3.5
dose accuracy
accuracy with which the NIS delivers a pre-set dose of medicinal product

3.6
“dose delivered” indication
dose number shown in the dose window indicating the amount of medicinal product delivered

NOTE 1 This applies to variable multi-dose NISs that allow the setting of a dose greater than the remaining volume.

NOTE 2 If the dose window indicates the amount of medicinal product yet to be delivered, then the “dose delivered” indication can be determined as the intended dose minus the indication of medicinal product yet to be delivered.

3.7
manufacturer-filled
container supplied to the user pre-filled by the manufacturer of medicinal products

NOTE This medicinal product can be in liquid form or lyophilized with diluent in the same container.

3.8
minimum deliverable dose
minimum dose that is ensured by the manufacturer to be delivered in a single-dose manufacturer-filled NIS designed to fully empty the container

3.9
NIS
needle-based injection system
injection system intended for parenteral administration by injection of medicinal products using a needle and a multi-dose or single-dose container

NOTE This term may also be referred to as “system” or “injector” in this part of ISO 11608.

3.10
pre-setting
procedure by which individual amounts of medicinal product can be selected for injection by the user

NOTE The doses may be pre-set by the manufacturer or the user.

3.11
residual scale
graduated scale which indicates the remainder of medicinal product in the container

3.12
user packaging
what is provided to the user with one or a collection of devices of the same item and from the same manufacturing batch, including the directions for use

3.13
user-filled
container that is filled or reconstituted (if in lyophilized form) by the user from a separate medicinal product or diluent container

4 Symbols and abbreviated terms

NIS Needle-based injection system.

V_{set} One of the three pre-set doses (expressed as a volume, in millilitres) used in determining the dose accuracy for a given NIS. V_{set} is defined as one of the following:

a) minimum dose ($V_{set} = V_{min}$) (specified in the instructions for use);

b) maximum dose ($V_{set} = V_{max}$) (specified in the instructions for use);

c) midpoint dose ($V_{set} = V_{mid}$), where V_{mid} is defined as the injector setting closest to ($V_{min} + V_{max}$)/2.

NOTE 1 Recommended doses as specified in the instructions for use may differ from the pre-set doses used for determining the dose accuracy.

NOTE 2 System designations B1 and D1 define V_{set} to be equal to the manufacturer-filled or user-filled volumes. System designations B2 and D2 define V_{set} to be equal to a single pre-set dose representing a portion of the manufacturer-filled or user-filled volumes. In the case of last-dose accuracy assessments for system designations A and C, V_{set} is equal to V_{mid}, the TP, or dose error (evaluated over a range of doses within a specified percentage of the TP).

V_{meas} The volumetric measurement value for a given V_{set}, expressed in millilitres.

G_{meas} The gravimetric measurement value for a given V_{set}, expressed in grams.

ρ Density, expressed in grams per millilitre.

p Probability content.

Y Number of pens required for a given test.

R Number of replicates required for a given test. A replicate is a random sequence of V_{min}, V_{mid}, and V_{max}. There are six possible replicates.

n Number of measurements, V_{meas}, to be made for each V_{set}.

$\bar{x}$ The sample mean; when based on a random sample, an estimate of the true mean:

$$\bar{x} = \sum V_{meas} / n \quad .$$

s The sample standard deviation; when based on a random sample, an estimate of the true standard deviation:

$$s = \left[\sum (V_{meas} - \bar{x})^2 / (n-1) \right]^{1/2} \quad .$$