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

Part 3: Containers and integrated fluid paths

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

Partie 3: Conteneurs et chemins de fluide intégrés

Reference number
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This third edition cancels and replaces the second edition (ISO 11608-3:2012), which has been technically revised.

The main changes are as follows:

— test methods and dimensions specific to traditional pen-injector “Type A” cartridges have been removed.

A list of all parts in the ISO 11608 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

This corrected version of ISO 11608-3:2022 incorporates the following corrections:

— "Unless otherwise justified" has been added to the beginning of 4.5.3.3.

Introduction

Developers and manufacturers of NIS are encouraged to investigate and determine if there are any other requirements relevant to the safety of their products.

Previous editions of this document focused on multi-dose pen-injector cartridges, important dimensions (e.g. inner diameter) and related attributes (e.g., disc seal eccentricity, meniscus) deemed critical for pen-injector form, fit, and function. The previous edition (i.e. ISO 11608-3:2012) included a more general discussion of "other containers" like syringes given their role in single dose NIS with automated functions (commonly referred to as auto-injectors).

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

Part 3: Containers and integrated fluid paths

1 Scope

This document specifies requirements and test methods for design verification of containers and integrated fluid paths used with Needle-Based Injection Systems (NISs) according to ISO 11608-1.

It is applicable to single and multi-dose containers either filled by the manufacturer (primary container closure) or by the end-user (reservoir) (e.g. cartridges, syringes) and fluid paths that are integrated with the NIS at the point of manufacture.

This document is also applicable to prefilled syringes (see ISO 11040-8) when used with a NIS (see also scope of ISO 11608-1:2022).

This document is not applicable to the following products:

— sterile hypodermic needles;

— sterile hypodermic syringes;

— sterile single-use syringes, with or without needle, for insulin;

— containers that can be refilled multiple times;

— containers intended for dental use;

— catheters or infusion sets that are attached or assembled separately by the user.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 7864:2016, *Sterile hypodermic needles for single use — Requirements and test methods*

ISO 8872, *Aluminium caps for transfusion, infusion and injection bottles — General requirements and test methods*

ISO 9626:2016, *Stainless steel needle tubing for the manufacture of medical devices — Requirements and test methods*

ISO 10555-1:2013, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

ISO 10555-5:2013, *Intravascular catheters — Sterile and single-use catheters — Part 5: Over-needle peripheral catheters*

ISO 10993-11, *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 10993-17, *Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances*

ISO 11040-4, *Prefilled syringes — Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling*

ISO 11040-5, *Prefilled syringes — Part 5: Plunger stoppers for injectables*

ISO 11040-6, *Prefilled syringes — Part 6: Plastic barrels for injectables and sterilized subassembled syringes ready for filling*

ISO 11040-8, *Prefilled syringes — Part 8: Requirements and test methods for finished prefilled syringes*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 11608-1:2022, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

ISO 13926-1, *Pen systems — Part 1: Glass cylinders for pen-injectors for medical use*

ISO 13926-2, *Pen systems — Part 2: Plunger stoppers for pen-injectors for medical use*

ISO 13926-3, *Pen systems — Part 3: Seals for pen-injectors for medical use*

ISO 21881, *Sterile packaged ready for filling glass cartridges*

ISO 80369-7, *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 11608-1 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
cartridge
container for the medicinal product that is closed on one end with a *cartridge cap* (3.2) and *disc* (3.5), and on the other end with a *plunger stopper* (3.8)

3.2
cartridge cap
component that attaches the *disc* (3.5) to the *cartridge* (3.1)

3.3
container closure integrity
CCI
adequacy of primary container closure to maintain a *sterile barrier* (3.10) against potential contaminants until the labelled expiration date or first intentional user interaction