BSI Standards Publication

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

Part 3: Containers and integrated fluid paths

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 11608-3:2022. It is identical to ISO 11608-3:2022. It supersedes BS EN ISO 11608-3:2012, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English Version

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 (ISO 11608-3:2022)

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung - Anforderungen und Prüfverfahren - Teil 3: NIS-Behälter und integrierte Flüssigkeitspfade (ISO 11608-3:2022)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

Ref. No. EN ISO 11608-3:2022 E

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European foreword

This document (EN ISO 11608-3:2022) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and 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of an identical text or by endorsement, at the latest by November 2022, and conflicting national standards shall be withdrawn at the latest by November 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 11608-3:2012.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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Endorsement notice

The text of ISO 11608-3:2022 has been approved by CEN as EN ISO 11608-3:2022 without any modification.

INTERNATIONAL STANDARD

ISO 11608-3

Third edition
2022-04

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

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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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).

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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.

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).

INTERNATIONAL STANDARD **ISO 11608-3:2022(E)**

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*