

Third edition
2022-04

Corrected version
2023-01

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

**Part 3:
Containers and integrated fluid paths**

iTEH Standards
Systèmes d'injection à aiguille pour usage médical — Exigences et
méthodes d'essai —
(<https://standards.iteh.ai>)
Partie 3: Conteneurs et chemins de fluide intégrés
Document Preview

[ISO 11608-3:2022](https://standards.iteh.ai/catalog/standards/iso/89b10c81-23e9-448b-908c-8c956f6974c9/iso-11608-3-2022)
<https://standards.iteh.ai/catalog/standards/iso/89b10c81-23e9-448b-908c-8c956f6974c9/iso-11608-3-2022>



Reference number
ISO 11608-3:2022(E)

© ISO 2022

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 11608-3:2022](#)

<https://standards.iteh.ai/catalog/standards/iso/89b10c81-23e9-448b-908c-8c956f6974c9/iso-11608-3-2022>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

Contents

Page

Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	3
4.1 General	3
4.2 Container integrity	4
4.2.1 Container Closure Integrity (CCI)	4
4.2.2 Resealability — All multi-dose cartridges or reservoirs with discs	4
4.2.3 Fragmentation (disc coring) – cartridges or reservoirs with discs	4
4.3 Cannula requirements (as part of the fluid path)	5
4.3.1 Rigid needles	5
4.3.2 Soft cannulas	5
4.4 Fluid line connections	5
4.5 Medicinal product compatibility	5
4.5.1 General	5
4.5.2 Medicinal product compatibility with reservoir and integrated fluid path materials	6
4.5.3 Reservoir and integrated fluid path particulate matter	6
4.5.4 Reservoir and fluid path pyrogenicity	6
4.5.5 Reservoir and integrated fluid path leachables	7
4.5.6 Sterilization of the reservoir and/or integrated fluid path	7
4.6 Medicinal product leakage	8
5 Test methods	8
5.1 Resealability for multi-dose cartridges or reservoirs	8
5.2 Fragmentation (disc coring) – cartridges or reservoirs	9
5.3 Sub-visible particulates	10
5.4 Visible particulates	10
6 Information supplied with the container	10
6.1 General	10
6.2 Marking on the unit packaging	10
Annex A (informative) Medicinal product compatibility references – Requirements, guidance, standards or compendia material	11
Annex B (informative) Historical references to previous editions	14
Annex C (informative) Theoretical support for resealability requirements	17
Annex D (informative) Reservoir and integrated fluid path leachables	20
Annex E (informative) Medicinal product compatibility	22
Annex F (informative) Primary container closure as compared to reservoir and fluid path	24
Bibliography	27

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).

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[ISO 11608-3:2022](#)

<https://standards.iteh.ai/catalog/standards/iso/89b10c81-23e9-448b-908c-8c956f6974c9/iso-11608-3-2022>