
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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Foreword

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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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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).