INTERNATIONAL STANDARD

**ISO 11608-1**

Third edition
2014-12-15

# 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*

Reference number
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ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web 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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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information.

The committee responsible for this document is ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This third edition cancels and replaces the second edition (ISO 11608-1:2012), 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*

This third edition of ISO 11608-1:2014 incorporates the following corrections:

a) in 4 Y: the term 'pens' is changed to 'NISs';

b) in 5.5 n): reference to ISO 11608-4 is deleted since 5.5. o) already addresses this;

c) in Table 3: the word "or" is changed to "and" so that it reads "Condition at 70 °C and −40 °C, then standard DA";

d) in 10.1, NOTE 1: Explanation is inserted;

e) in 10.5 a) designation B is deleted;

f) in 10.5 b) designation D is deleted;

g) in 10.5 b) 3) iv) the term 'replacements' is changed to 'obvious container failures';

h) in 10.5 d) 2) iv) the term ‘replacements’ is changed to ‘obvious container failures’;

i) in 10.8 the temperature range is changed from (25 ± 3) °C to (5 ± 3) °C;

j) in 10.10.4 and 10.10.5 “five NISs” is changed to “20 NISs” according to Table 3;

k) in Table 3 – references to 10.10.4 and 10.10.5 are added under column A;

l) in 13.2.3 “unit packaging” has been changed into “user packaging”.