

ICS 11.040.25

**Needle-based injection systems for medical use –
Requirements and test methods –
Part 5: Automated functions (ISO 11608-5:2012);
English version EN ISO 11608-5:2012,
English translation of DIN EN ISO 11608-5:2013-01**

Kanülenbasierte Injektionssysteme zur medizinischen Verwendung –
Anforderungen und Prüfverfahren –
Teil 5: Automatisierte Funktionen (ISO 11608-5:2012);
Englische Fassung EN ISO 11608-5:2012,
Englische Übersetzung von DIN EN ISO 11608-5:2013-01

Systèmes d'injection à aiguille pour usage médical –
Exigences et méthodes d'essai –
Partie 5: Fonctions automatisées (ISO 11608-5:2012);
Version anglaise EN ISO 11608-5:2012,
Traduction anglaise de DIN EN ISO 11608-5:2013-01

Document comprises 24 pages

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In case of doubt, the German-language original shall be considered authoritative.

A comma is used as the decimal marker.

National foreword

This document (EN ISO 11608-5:2012) has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and intravascular catheters” in collaboration with Technical Committee CEN/TC 205 “Non-active medical devices” (Secretariat: DIN, Germany).

The responsible German body involved in its preparation was the *Normenausschuss Medizin* (Medical Standards Committee), Working Committee NA 063-02-01 AA *Injektionssysteme*.

The DIN Standards corresponding to the International Standards referred to in this document are as follows:

ISO 8537	DIN EN ISO 8537
ISO 9000	DIN EN ISO 9000
ISO 13485	DIN EN ISO 13485
ISO 14253-1	DIN EN ISO 14253-1
ISO 14971	DIN EN ISO 14971
ISO 16926-6	DIN ISO 16269-6
ISO 23908	DIN EN ISO 23908

DIN EN 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*

National Annex NA (informative)

Bibliography

DIN EN 60068-2-30, *Environmental testing — Part 2-30: Tests — Test Db: Damp heat, cyclic (12 h + 12 h cycle)*

DIN EN ISO 8537, *Sterile single-use syringes, with or without needle, for insulin*

DIN EN ISO 9000, *Quality management systems — Fundamentals and vocabulary*

DIN EN ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

DIN EN ISO 14253-1, *Geometrical product specifications (GPS) — Inspection by measurement of workpieces and measuring equipment — Part 1: Decision rules for proving conformance or non-conformance with specifications*

DIN EN ISO 14971, *Medical devices — Application of risk management to medical devices*

DIN ISO 16269-6, *Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals*

DIN EN ISO 23908, *Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling*

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