

# DIN EN ISO 11608-1:2015-04 (E)

## Needle-based injection systems for medical use - Requirements and test methods - Part 1: Needle-based injection systems (ISO 11608-1:2014)

---

<b>Contents</b>		<b>Page</b>
Foreword .....		4
Introduction .....		5
1	Scope .....	6
2	Normative references .....	6
3	Terms and definitions .....	6
4	Symbols and abbreviated terms .....	8
5	Requirements .....	9
5.1	General .....	9
5.2	System designations .....	10
5.3	Risk analysis requirements .....	10
5.4	Uncertainty of measurement and conformance with specifications .....	10
5.5	General design requirements .....	10
6	Reagent and apparatus .....	12
6.1	General .....	12
6.2	Test liquid .....	12
6.3	Balance .....	12
6.4	Test surface for free-fall testing .....	12
7	Determination of dose accuracy .....	12
7.1	General .....	12
7.2	Dosing regions .....	13
7.3	Dose settings .....	14
7.3.1	Multi-dose containers (system designations A and C) .....	14
7.3.2	Single-dose containers (system designations B and D) .....	14
7.4	Assessment .....	14
7.4.1	General .....	14
7.4.2	Determination of dose accuracy limits .....	15
7.4.3	Determination of last-dose error and last-dose accuracy limits (system designations A and C) .....	16
7.4.4	Calculation of dose delivery efficiency (system designations B1 and D1, user-filled) .....	16
7.4.5	Calculation of tolerance intervals .....	17
8	Preparation and operation of NISs .....	17
9	Test matrix .....	18
10	Test descriptions .....	21
10.1	General .....	21
10.2	Cool, standard and warm atmosphere testing .....	21
10.2.1	Pre-conditioning .....	21
10.2.2	Testing .....	21
10.3	Last-dose testing (system designations A and C only) .....	22
10.3.1	General .....	22
10.3.2	Pre-conditioning .....	22

10.3.3	Testing .....	22
10.4	Life-cycle testing (systems designations A and B only) -- Pre-conditioning .....	22
10.5	Free-fall testing .....	22
10.6	Dry-heat and cold-storage testing -- Pre-conditioning .....	24
10.7	Damp-heat testing (system designations A and B only) -- Pre-conditioning .....	24
10.8	Cyclical testing (system designations A and B only) -- Pre-conditioning .....	24
10.9	Vibration testing -- Pre-conditioning .....	25
10.10	Electromagnetic compatibility (EMC) (systems with electronics only) .....	25
10.10.1	General .....	25
10.10.2	Exposure to electrostatic discharge -- Pre-conditioning .....	25
10.10.3	Radiated radio-frequency (RF) fields -- Pre-conditioning .....	25
10.10.4	Compliance criteria for electrostatic discharge .....	25
10.10.5	Radiated radio-frequency (RF) fields .....	26
11	Inspection .....	26
11.1	Visual inspection .....	26
11.2	Container inspection .....	26
11.3	Dose accuracy acceptance criteria .....	26
12	Test report .....	27
13	Information supplied by the manufacturer .....	27
13.1	General .....	27
13.2	Marking .....	27
13.2.1	General .....	27
13.2.2	Marking on the NIS .....	28
13.2.3	Marking on the user packaging .....	28
13.3	Instructions for use .....	28
	Annex A (informative) Dose replicates, accuracy and testing rationale .....	30
	Annex B (normative) One- and two-sided tolerance limit factors, k .....	34
	Bibliography .....	46
	Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC .....	45