

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)

Contents		Page
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