

DIN EN ISO 11608-4:2022-09 (E)

Needle-based injection systems for medical use - Requirements and test methods - Part 4: Needle-based injection systems containing electronics (ISO 11608-4:2022)

Contents		Page
European foreword		4
Foreword		5
Introduction		6
1 Scope		7
2 Normative references		7
3 Terms and definitions		9
4 Abbreviated terms		17
5 General requirements		17
5.1	Conditions for application of NIS-E	17
5.2	General design requirements	18
5.3	Risk approach and usability engineering	18
6 General requirements for testing		19
6.1	Type tests	19
6.2	Number of samples	19
6.3	Ambient temperature, humidity, atmospheric pressure	24
7 Identification and marking of NIS-E		24
8 Protection against electrical hazards		24
8.1	General	24
8.2	Humidity preconditioning treatment	24
8.3	Requirements and test methods	25
8.3.1	General	25
8.3.2	Applied parts	25
8.3.3	Requirements related to power sources	27
8.3.4	Limitation of current for accessible parts and applied parts	28
8.4	Separation of parts (Type X and Type Y)	28
8.4.1	Means of protection (MOP)	28
8.4.2	Separation of patient connection	29
8.4.3	Maximum mains voltage	30
8.4.4	Working voltage	30
8.5	Patient leakage current and touch current (Type X and Type Y NIS-E)	31
8.5.1	General	31
8.5.2	Measurement of patient leakage current	35
8.5.3	Measurement of touch current	38
8.6	Insulation (Type X and Type Y)	39
8.6.1	General	39
8.6.2	Distance through solid insulation or use of thin sheet material	39
8.6.3	Dielectric strength	40
8.7	Insulation other than wire insulation	40
8.7.1	Mechanical strength and resistance to heat	40
8.8	Creepage distances and air clearances (Type X and Type Y NIS-E)	41
8.8.1	General	41

8.9	Specific hazardous situations	42
8.9.1	General	42
8.9.2	Emissions, deformation of enclosure or exceeding maximum temperature	42
8.9.3	Exceeding leakage current or voltage limits	44
8.9.4	Specific mechanical hazards	44
8.10	Single fault conditions (Type X and Type Y)	44
8.10.1	General	44
8.10.2	Failure of thermostats and temperature limiting devices	44
8.10.3	Leakage of liquid from batteries	45
8.10.4	Locking of moving parts	45
8.10.5	Additional test criteria for motor-operated NIS-E	45
8.10.6	NIS-E intended for used in conjunction with oxygen rich environments	45
8.10.7	Power supply (Type Y)	45
8.11	Pre-conditioning for the influence of fluid leakage	46
9	Electromagnetic compatibility (EMC)	47
9.1	General requirements	47
9.1.1	Risk approach process for NIS-E	47
9.1.2	Non-medical electrical equipment used with NIS-E	47
9.1.3	General test conditions	48
9.2	NIS-E identification, marking and documents	53
9.2.1	Instruction for use in relation to EMC	53
9.2.2	Documentation of the tests	53
9.3	Electromagnetic emissions requirements for NIS-E	54
9.3.1	Protection of radio services and other equipment	54
9.3.2	Protection of the public mains network	54
9.3.3	Emissions requirements summary (Type X and Type Y)	55
9.4	Electromagnetic immunity requirements for NIS-E	55
9.4.1	General	55
9.4.2	Operating modes	57
9.4.3	Non-medical electrical equipment	57
9.4.4	Immunity test levels	57
9.4.5	Immunity to proximity fields from RF wireless communications equipment	62
9.4.6	Immunity to proximity magnetic fields in the frequency range 9 kHz to 13,56 MHz	64
10	Protection against mechanical hazards	64
10.1	General	64
10.2	Shock	64
10.3	Vibration	64
10.3.1	Sinusoidal vibration	64
10.3.2	Random vibration	64
10.4	Impact of OBDS enclosures	65
10.5	Push	65
11	Programmable NIS-E	65
	Annex A (informative) Identification of immunity pass/fail criteria	66
	Annex B (informative) Rationale for using 240 V for testing some requirements	68
	Bibliography	69