

# 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
<b>1 Scope .....</b>	<b>7</b>
<b>2 Normative references .....</b>	<b>7</b>
<b>3 Terms and definitions .....</b>	<b>9</b>
<b>4 Abbreviated terms .....</b>	<b>17</b>
<b>5 General requirements .....</b>	<b>17</b>
5.1 Conditions for application of NIS-E .....	17
5.2 General design requirements .....	18
5.3 Risk approach and usability engineering .....	18
<b>6 General requirements for testing .....</b>	<b>19</b>
6.1 Type tests .....	19
6.2 Number of samples .....	19
6.3 Ambient temperature, humidity, atmospheric pressure .....	24
<b>7 Identification and marking of NIS-E .....</b>	<b>24</b>
<b>8 Protection against electrical hazards .....</b>	<b>24</b>
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
<b>9</b>	<b>Electromagnetic compatibility (EMC)</b>	<b>47</b>
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
<b>10</b>	<b>Protection against mechanical hazards</b>	<b>64</b>
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
<b>11</b>	<b>Programmable NIS-E</b>	<b>65</b>
	<b>Annex A (informative) Identification of immunity pass/fail criteria</b>	<b>66</b>
	<b>Annex B (informative) Rationale for using 240 V for testing some requirements</b>	<b>68</b>
	<b>Bibliography</b>	<b>69</b>