

# DIN EN ISO 21649:2023-06 (E)

## Needle-free injection systems for medical use - Requirements and test methods (ISO 21649:2023)

---

<b>Contents</b>		<b>Page</b>
<b>European foreword</b>	.....	<b>4</b>
<b>Foreword</b>	.....	<b>5</b>
<b>Introduction</b>	.....	<b>7</b>
<b>1 Scope</b>	.....	<b>8</b>
<b>2 Normative references</b>	.....	<b>8</b>
<b>3 Terms and definitions</b>	.....	<b>9</b>
<b>4 Symbols</b>	.....	<b>11</b>
<b>5 Requirements</b>	.....	<b>12</b>
5.1	General requirements	12
5.2	Noise requirements	13
5.3	Dose accuracy specification requirements	14
5.4	Usability engineering	14
5.5	Risk approach	14
5.6	Uncertainty of measurements and conformance with specifications	14
5.7	Performance profile requirements	15
5.8	Test requirements	15
5.8.1	NFISs subjected to standard, cool and hot atmospheres and after claimed lifetime testing (in-use conditions)	15
5.8.2	Dry heat storage - Preconditioning	16
5.8.3	Damp heat storage - Preconditioning	16
5.8.4	Cold storage - Preconditioning	16
5.8.5	Cyclical testing - Preconditioning	17
5.8.6	Free fall - Preconditioning	17
5.8.7	Vibration and shock - Preconditioning	17
5.8.8	Transport - Preconditioning	17
5.8.9	NFISs with electrical components subjected to electromagnetic compatibility (EMC)	18
5.8.10	Water and dust resistance	18
5.8.11	Auto-disable feature	18
<b>6 Test methods</b>	.....	<b>19</b>
6.1	General	19
6.2	Test procedures	20
6.2.1	General	20
6.2.2	NFISs subjected to standard, cool and hot atmospheres and claimed lifetime test	21
6.2.3	NFISs subjected to dry heat storage atmosphere	23
6.2.4	NFISs subjected to damp-heat storage atmosphere	23
6.2.5	NFISs subjected to cold storage atmosphere	24
6.2.6	NFISs subjected to a cyclical atmosphere	24
6.2.7	NFISs subjected to free fall	24
6.2.8	NFISs subjected to vibration and shock	25
6.2.9	NFISs with electrical components subjected to electromagnetic compatibility (EMC) testing	26
6.2.10	Noise testing	27
6.2.11	Water and dust resistance	28
6.2.12	Auto-disable feature	29

6.3	Test evaluations.....	29
6.3.1	Dose accuracy.....	29
6.3.2	Inspection.....	30
<b>7</b>	<b>Test report.....</b>	<b>31</b>
<b>8</b>	<b>Information supplied with the NFIS.....</b>	<b>31</b>
8.1	General.....	31
8.2	Marking.....	32
8.3	Instructions for use.....	32
<b>Annex A</b>	<b>(informative) Two-sided tolerance limit factors (<i>k</i>).....</b>	<b>33</b>
<b>Annex B</b>	<b>(informative) Examples of accuracy limit calculations and random settings.....</b>	<b>39</b>
<b>Annex C</b>	<b>(normative) Instructions for use, marking and age warning.....</b>	<b>40</b>
<b>Annex D</b>	<b>(informative) Example for <i>k</i> factor.....</b>	<b>42</b>
<b>Bibliography</b>	<b>.....</b>	<b>43</b>