DIN EN ISO 21649:2023-06 (E)

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

Contents

Page

European foreword ... **4**

Foreword ... **5**

Introduction ... **7**

1 Scope ... **8**

2 Normative references ... **8**

3 Terms and definitions ... **9**

4 Symbols ... **11**

5 Requirements ... **12**
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

6 Test methods ... **19**
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
7 Test report 31
8 Information supplied with the NFIS 31
8.1 General 31
8.2 Marking 32
8.3 Instructions for use 32
Annex A (informative) **Two-sided tolerance limit factors (*k*) 33**
Annex B (informative) **Examples of accuracy limit calculations and random settings 39**
Annex C (normative) **Instructions for use, marking and age warning 40**
Annex D (informative) **Example for *k* factor 42**
Bibliography 43