DIN EN ISO 11608-5:2023-05 (E)

Needle-based injection systems for medical use - Requirements and test methods - Part 5: Automated functions (ISO 11608-5:2022)

Contents

Page

European foreword ... **3**

Foreword ... **4**

Introduction ... **5**

1 Scope ... **6**

2 Normative references ... **6**

3 Terms and definitions ... **7**

4 Requirements ... **9**
- 4.1 General requirements ... 9
- 4.2 Medicinal product preparation ... 10
- 4.3 Needle preparation ... 11
- 4.4 Needle hiding ... 11
- 4.5 Priming ... 11
- 4.6 Dose setting ... 11
- 4.7 Needle insertion ... 11
- 4.8 Injection depth control ... 11
- 4.9 Dose delivery ... 12
- 4.10 Recording of device functions ... 12
- 4.11 Needle retraction ... 12
  - 4.11.1 Completion of dose delivery ... 12
  - 4.11.2 Needle retraction distance ... 12
  - 4.11.3 Communication of completion ... 12
- 4.12 Disabling the NIS-AUTO ... 12
- 4.13 Needle shielding ... 13
  - 4.13.1 General ... 13
  - 4.13.2 Needle shielding before injection ... 13
  - 4.13.3 Needle shielding after injection ... 13
- 4.14 Needle removal from the NIS-AUTO ... 13

5 Test methods ... **13**
- 5.1 General ... 13
- 5.2 Test conditions ... 14
- 5.3 Actuation ... 14
- 5.4 Medicinal product preparation ... 14
- 5.5 Needle inspection ... 14
- 5.6 Needle hiding ... 14
- 5.7 Priming ... 15
- 5.8 Needle extension ... 15
- 5.9 Injection time ... 15
- 5.10 Dose accuracy ... 16
- 5.11 Retracted position ... 16
- 5.12 Disabling the NIS-AUTO ... 16
- 5.13 Needle shielding ... 16
  - 5.13.1 Needle shielding before and after injection ... 16
  - 5.13.2 Needle shielding after free fall ... 16

6 Information supplied with the NIS-AUTO ... **16**

Annex A (informative) **Rationale for requirements** **17**
Annex B (informative) **Example of a test method for dose accuracy at intended injection depth** **19**
Annex C (informative) **Needle extension and intended injection depth** **21**
Bibliography **27**