

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