

ISO 11608-6:2022-04 (E)

Needle-based injection systems for medical use - Requirements and test methods - Part 6: On-body delivery systems

| Contents | | Page |
|--------------------|---|-------------|
| Foreword | | iv |
| Introduction | | v |
| 1 | Scope | 1 |
| 2 | Normative references | 1 |
| 3 | Terms and definitions | 1 |
| 4 | Requirements | 3 |
| 4.1 | General | 3 |
| 4.2 | Risk assessment | 3 |
| 4.3 | Usability engineering | 3 |
| 4.4 | Uncertainty of measurement and conformance with specifications | 3 |
| 4.5 | General design requirements | 3 |
| 4.6 | Physical or mechanical requirements and test methods | 3 |
| 4.6.1 | General | 3 |
| 4.6.2 | Systems comprising rigid needles | 3 |
| 4.6.3 | Systems comprising a soft cannula(s) | 3 |
| 4.6.4 | Leakage from the OBDS | 3 |
| 4.6.5 | Means of attachment | 4 |
| 4.6.6 | Occlusion | 4 |
| 4.7 | Functional performance requirements and test methods | 5 |
| 4.7.1 | General | 5 |
| 4.7.2 | Dosing requirements and methods | 5 |
| 4.7.3 | Sharps injury protection | 6 |
| 4.7.4 | Automated functions | 6 |
| 4.7.5 | Injection depth and needle extension | 7 |
| 4.8 | Biological requirements of the OBDS | 7 |
| 4.8.1 | Sterility of OBDS | 7 |
| 4.8.2 | Biocompatibility | 7 |
| 4.9 | Medicinal product compatibility | 7 |
| 4.9.1 | General | 7 |
| 4.9.2 | Particulates | 7 |
| 4.9.3 | Pyrogenicity | 7 |
| 4.9.4 | Extractable/leachables | 7 |
| 4.10 | Electrical safety and software requirements | 8 |
| 4.10.1 | Electrical safety | 8 |
| 4.10.2 | Software | 8 |
| 5 | Inspection | 8 |
| 6 | Information supplied by the manufacturer | 8 |
| | Annex A (informative) Test methods for adhesion | 9 |
| | Annex B (informative) Dose delivery profiles | 10 |
| | Annex C (informative) In vitro methods in relation to needle/cannula displacement | 16 |
| | Bibliography | 17 |