ISO 11608-2:2012-04 (E)

Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Requirements 3
4.1 Materials 3
4.2 Dimensions 3
4.3 Determinationofflowratethroughtheneedle 3
4.4 Bond between hub and needle tube 3
4.5 Needle points 4
4.6 Freedom from defects 4
4.7 Lubrication 4
4.8 Dislocationofmeasuringpointatpatientend 4
4.9 Determination of functional compatibility with needle-based injection systems 4
4.10 Ease of assembly and disassembly 4
4.11 Sterility 4

5 Sampling 4

6 Pre-conditioningofneedles 5
6.1 Pre-conditioninginadry-heatatmosphere 5
6.2 Pre-conditioninginacold-storageatmosphere 5
6.3 Pre-conditioninginacyclicalatmosphere 5

7 Standard atmosphere and apparatus for tests 6
7.1 General 6
7.2 Standard test atmosphere 6
7.3 Testgauge 6

8 Determinationofdislocationofmeasuringpointatpatientend 7

9 Bond between hub and needle tube 8

10 Packaging 8

11 Testmethodforvalidatingthecompatibilityofneedlesandinjectorsystems 8
11.1 Principle 8
11.2 Apparatus and equipment 9
11.3 Sample quantity requirements 9
11.4 Procedure 9
11.5 Acceptance criteria 11
11.6 Test report 12

12 Information supplied by the manufacturer 12
12.1 General 12

12.2 Marking 12
12.3 Instructions for use 14

Annex A (normative)Determinationofflowratethroughneedle 15

Bibliography 17