DIN EN ISO 11608-2:2012-12 (E)

Needle-based injection systems for medical use - Requirements and test methods - Part 2: Needles (ISO 11608-2:2012)

Contents

Page

Foreword 3

Introduction 4

1 Scope 5

2 Normative references 5

3 Terms and definitions 5

4 Requirements 7
4.1 Materials 7
4.2 Dimensions 7
4.3 Determination of flow rate through the needle 7
4.4 Bond between hub and needle tube 7
4.5 Needle points 8
4.6 Freedom from defects 8
4.7 Lubrication 8
4.8 Dislocation of measuring point at the patient-end 8
4.9 Determination of functional compatibility with needle-based injection systems 8
4.10 Ease of assembly/disassembly 8
4.11 Sterility 8

5 Sampling 8

6 Pre-conditioning of needles 9
6.1 Pre-conditioning in dry heat atmosphere 9
6.2 Pre-conditioning in cold storage atmosphere 9
6.3 Pre-conditioning in cyclical atmosphere 9

7 Standard atmosphere and apparatus for tests 10
7.1 General 10
7.2 Standard test atmosphere 10
7.3 Test gauge 10

8 Determination of dislocation of measuring point at the patient-end 11

9 Bond between hub and needle tube 12

10 Packaging 12

11 Test method for needle/injector systems compatibility validation 12
11.1 Principle 12
11.2 Apparatus/equipment 13
11.3 Sample quantity requirements 13
11.4 Procedure 13
11.5 Acceptance criteria 15
11.6 Test report 16

12 Information supplied by the manufacturer 16
12.1 General 16

12.2 Marking 16
12.3 Instructions for use 18

Annex A (normative) Determination of flow rate through needle 19

Bibliography 21