

# ISO 11608-2:2000-12 (E)

## Pen-injectors for medical use - Part 2: Needles; Requirements and test methods

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	1
4	Requirements .....	2
4.1	Colour coding .....	2
4.2	Materials .....	2
4.3	Dimensions .....	2
4.4	Patency of lumen .....	3
4.5	Needle points .....	3
4.6	Freedom from defects .....	3
4.7	Lubrication .....	3
4.8	Dislocation of measuring point at the patient-end of Type A needles .....	4
4.9	Bond between hub and needle tube .....	4
4.10	Unscrewing torque of the needle .....	4
4.11	Ease of assembly/disassembly .....	4
4.12	Sterility .....	4
5	Sampling .....	4
6	Preconditioning of needles .....	5
6.1	Preconditioning in dry heat atmosphere .....	5
6.2	Preconditioning in cold storage atmosphere .....	5
6.3	Preconditioning in cyclical atmosphere .....	5
7	Standard atmosphere and apparatus for tests .....	6
7.1	Standard test atmosphere .....	6
7.2	Test apparatus .....	6
8	Determination of dislocation of measuring point at the patient-end of Type A needles .....	7
9	Bond between hub and needle tube .....	7
10	Unscrewing torque of the needle .....	7
11	Packaging .....	8
12	Information supplied by the manufacturer .....	8
12.1	General .....	8
12.2	Marking .....	8
12.3	Instructions for use .....	9
Bibliography .....		10