

# 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
<b>1</b>	<b>Scope .....</b>	<b>1</b>
<b>2</b>	<b>Normative references .....</b>	<b>1</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>1</b>
<b>4</b>	<b>Requirements .....</b>	<b>2</b>
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
<b>5</b>	<b>Sampling .....</b>	<b>4</b>
<b>6</b>	<b>Preconditioning of needles .....</b>	<b>5</b>
6.1	Preconditioning in dry heat atmosphere .....	5
6.2	Preconditioning in cold storage atmosphere .....	5
6.3	Preconditioning in cyclical atmosphere .....	5
<b>7</b>	<b>Standard atmosphere and apparatus for tests .....</b>	<b>6</b>
7.1	Standard test atmosphere .....	6
7.2	Test apparatus .....	6
<b>8</b>	<b>Determination of dislocation of measuring point at the patient-end of Type A needles .....</b>	<b>7</b>
<b>9</b>	<b>Bond between hub and needle tube .....</b>	<b>7</b>
<b>10</b>	<b>Unscrewing torque of the needle .....</b>	<b>7</b>
<b>11</b>	<b>Packaging .....</b>	<b>8</b>
<b>12</b>	<b>Information supplied by the manufacturer .....</b>	<b>8</b>
12.1	General .....	8
12.2	Marking .....	8
12.3	Instructions for use .....	9
Bibliography .....		10