

# DIN ISO 11040-4:2017-07 (E)

## Prefilled syringes - Part 4: Glass barrels for injectables and sterilized subassembled syringes ready for filling (ISO 11040-4:2015)

---

<b>Contents</b>	<b>Page</b>
<b>National foreword</b> .....	<b>3</b>
<b>National Annex (informative) Bibliography</b> .....	<b>4</b>
<b>Foreword</b> .....	<b>6</b>
<b>Introduction</b> .....	<b>8</b>
<b>1 Scope</b> .....	<b>9</b>
<b>2 Normative references</b> .....	<b>9</b>
<b>3 Terms and definitions</b> .....	<b>10</b>
<b>4 General requirements</b> .....	<b>11</b>
4.1 Quality systems .....	11
4.2 Testing .....	11
4.3 Documentation .....	11
<b>5 Syringe barrel</b> .....	<b>12</b>
5.1 Design including dimensions .....	12
5.2 Functional testing of Luer connection .....	15
5.3 Material .....	15
5.4 Performance requirements .....	15
5.4.1 Hydrolytic resistance .....	15
5.4.2 Annealing quality .....	15
5.4.3 Lubrication of the inner surface .....	15
5.4.4 Flange breakage resistance .....	15
5.4.5 Luer cone breakage resistance .....	16
<b>6 Sterilized subassembled syringes ready for filling</b> .....	<b>16</b>
6.1 General .....	16
6.2 Sterility .....	16
6.3 Pyrogenicity/endotoxins .....	17
6.4 Particles .....	17
6.5 Additional requirements to specific components of sterilized subassembled syringes ready for filling .....	17
6.5.1 Barrel .....	17
6.5.2 Needle .....	18
6.5.3 Closure system .....	19
6.6 Closure system barrel integrity .....	20
<b>7 Packaging</b> .....	<b>20</b>
<b>8 Labelling</b> .....	<b>20</b>
<b>Annex A (informative) Examples of types of sterilized subassembled syringes ready for filling</b> .....	<b>21</b>
<b>Annex B (informative) Head designs</b> .....	<b>23</b>
<b>Annex C (normative) Test methods for syringe barrels</b> .....	<b>25</b>
<b>Annex D (informative) Sample preparation for endotoxin and particulate determination</b> .....	<b>31</b>
<b>Annex E (informative) Glide force test method to evaluate syringe lubrication</b> .....	<b>35</b>
<b>Annex F (informative) Needle penetration test</b> .....	<b>38</b>
<b>Annex G (normative) Test methods for closure systems</b> .....	<b>41</b>
<b>Annex H (informative) Dye solution tightness test</b> .....	<b>56</b>
<b>Bibliography</b> .....	<b>58</b>