

# DIN ISO 21881:2020-12 (E)

## Sterile packaged ready for filling glass cartridges (ISO 21881:2019)

---

<b>Contents</b>		<b>Page</b>
<b>National foreword</b> .....		<b>4</b>
<b>National Annex NA (informative) Bibliography</b> .....		<b>5</b>
<b>Foreword</b> .....		<b>7</b>
<b>Introduction</b> .....		<b>8</b>
<b>1</b>	<b>Scope</b> .....	<b>9</b>
<b>2</b>	<b>Normative references</b> .....	<b>9</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>9</b>
<b>4</b>	<b>Quality system</b> .....	<b>11</b>
	4.1 General .....	11
	4.2 Testing .....	11
<b>5</b>	<b>Process description and requirements</b> .....	<b>11</b>
	5.1 Washing .....	11
	5.2 Drying .....	11
	5.3 Lubrication .....	11
	5.4 Capping and crimping .....	12
	5.5 Plunger insertion .....	12
	5.6 Packaging .....	12
	5.7 Sterilization .....	12
<b>6</b>	<b>Requirements for glassware</b> .....	<b>12</b>
	6.1 General .....	12
	6.2 Material .....	12
	6.3 Dimensions .....	13
	6.4 Particles .....	13
	6.4.1 Visible particles .....	13
	6.4.2 Sub-visible particles .....	13
	6.5 Bacterial endotoxin level .....	13
<b>7</b>	<b>Requirements for packaging system</b> .....	<b>14</b>
	7.1 General .....	14
	7.2 Nest and tub configuration .....	15
	7.3 Tray configuration .....	15
	7.4 Nest .....	15
	7.5 Tub and tray .....	16
	7.6 Insert liner .....	16
	7.7 Sealing lid .....	16
	7.8 Protective bag .....	16
	7.9 Information to be provided by the manufacturer .....	17
<b>8</b>	<b>Marking of the tub or tray</b> .....	<b>17</b>
<b>9</b>	<b>Labelling</b> .....	<b>18</b>

<b>Annex A</b> (informative) <b>Design of tub</b> .....	<b>19</b>
<b>Annex B</b> (informative) <b>Design of nest</b> .....	<b>20</b>
<b>Annex C</b> (informative) <b>Design of tray</b> .....	<b>21</b>
<b>Annex D</b> (normative) <b>Glide force test method to evaluate cartridge lubrication</b> .....	<b>22</b>
<b>Annex E</b> (informative) <b>Schematic illustrations of examples for the orientation of tubs or trays within the protective bag</b> .....	<b>24</b>
<b>Annex F</b> (normative) <b>Closure systems liquid leakage</b> .....	<b>27</b>
<b>Annex G</b> (informative) <b>Sample preparation for endotoxin and particulate determination</b> .....	<b>29</b>
<b>Annex H</b> (informative) <b>Product and packaging configuration</b> .....	<b>33</b>
<b>Bibliography</b> .....	<b>36</b>