

# ISO 1135-4:2004-07 (E)

## Transfusion equipment for medical use - Part 4: Transfusion sets for single use

---

<b>Contents</b>		<b>Page</b>
<b>1</b>	<b>Scope</b> .....	<b>1</b>
<b>2</b>	<b>Normative references</b> .....	<b>1</b>
<b>3</b>	<b>General requirements</b> .....	<b>1</b>
<b>3.1</b>	<b>Nomenclature for components of the transfusion set</b> .....	<b>1</b>
<b>3.2</b>	<b>Maintenance of sterility</b> .....	<b>3</b>
<b>3.3</b>	<b>Designation</b> .....	<b>3</b>
<b>4</b>	<b>Materials</b> .....	<b>4</b>
<b>5</b>	<b>Physical requirements</b> .....	<b>4</b>
<b>5.1</b>	<b>Particulate contamination</b> .....	<b>4</b>
<b>5.2</b>	<b>Leakage</b> .....	<b>4</b>
<b>5.3</b>	<b>Tensile strength</b> .....	<b>4</b>
<b>5.4</b>	<b>Closure-piercing device</b> .....	<b>4</b>
<b>5.5</b>	<b>Air-inlet device</b> .....	<b>5</b>
<b>5.6</b>	<b>Tubing</b> .....	<b>5</b>
<b>5.7</b>	<b>Filter for blood and blood components</b> .....	<b>5</b>
<b>5.8</b>	<b>Drip chamber and drip tube</b> .....	<b>5</b>
<b>5.9</b>	<b>Flow regulator</b> .....	<b>5</b>
<b>5.10</b>	<b>Flow rate of blood and blood components</b> .....	<b>5</b>
<b>5.11</b>	<b>Injection site</b> .....	<b>6</b>
<b>5.12</b>	<b>Male conical fitting</b> .....	<b>6</b>
<b>5.13</b>	<b>Protective caps</b> .....	<b>6</b>
<b>6</b>	<b>Chemical requirements</b> .....	<b>6</b>
<b>6.1</b>	<b>Reducing (oxidizable) matter</b> .....	<b>6</b>
<b>6.2</b>	<b>Metal ions</b> .....	<b>6</b>
<b>6.3</b>	<b>Titration acidity or alkalinity</b> .....	<b>6</b>
<b>6.4</b>	<b>Residue on evaporation</b> .....	<b>6</b>
<b>6.5</b>	<b>UV absorption of extract solution</b> .....	<b>6</b>
<b>7</b>	<b>Biological requirements</b> .....	<b>7</b>
<b>7.1</b>	<b>General</b> .....	<b>7</b>
<b>7.2</b>	<b>Sterility</b> .....	<b>7</b>
<b>7.3</b>	<b>Pyrogenicity</b> .....	<b>7</b>
<b>7.4</b>	<b>Haemolysis</b> .....	<b>7</b>
<b>7.5</b>	<b>Toxicity</b> .....	<b>7</b>
<b>8</b>	<b>Labelling</b> .....	<b>7</b>
<b>8.1</b>	<b>Unit container</b> .....	<b>7</b>
<b>8.2</b>	<b>Shelf or multi-unit container</b> .....	<b>8</b>
<b>9</b>	<b>Packaging</b> .....	<b>8</b>
<b>Annex A (normative) Physical tests</b> .....		<b>9</b>
<b>Annex B (normative) Chemical tests</b> .....		<b>13</b>
<b>Annex C (normative) Biological tests</b> .....		<b>15</b>
<b>Bibliography</b> .....		<b>16</b>