

# ISO 13408-5:2006-11 (E)

## Aseptic processing of health care products - Part 5: Sterilization in place

---

<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>Terms and definitions .....</b>	<b>2</b>
<b>4</b>	<b>Quality system elements .....</b>	<b>3</b>
<b>4.1</b>	<b>General .....</b>	<b>3</b>
<b>4.2</b>	<b>Management responsibility .....</b>	<b>3</b>
<b>4.3</b>	<b>Design control .....</b>	<b>3</b>
<b>4.4</b>	<b>Measuring instruments and measuring systems .....</b>	<b>3</b>
<b>5</b>	<b>Process and equipment characterization .....</b>	<b>4</b>
<b>5.1</b>	<b>General concepts .....</b>	<b>4</b>
<b>5.2</b>	<b>Effectiveness of sterilization in place (SIP) .....</b>	<b>4</b>
<b>5.3</b>	<b>Equipment .....</b>	<b>4</b>
<b>6</b>	<b>Sterilizing agent characterization .....</b>	<b>6</b>
<b>6.1</b>	<b>Selection of sterilizing agent(s) .....</b>	<b>6</b>
<b>6.2</b>	<b>Quality of sterilizing agent(s) .....</b>	<b>6</b>
<b>6.3</b>	<b>Safety and the environment .....</b>	<b>6</b>
<b>7</b>	<b>SIP process .....</b>	<b>6</b>
<b>7.1</b>	<b>Process parameters .....</b>	<b>6</b>
<b>7.2</b>	<b>Cycle development .....</b>	<b>7</b>
<b>8</b>	<b>Validation .....</b>	<b>7</b>
<b>8.1</b>	<b>Validation protocol .....</b>	<b>7</b>
<b>8.2</b>	<b>Design qualification .....</b>	<b>7</b>
<b>8.3</b>	<b>Installation qualification .....</b>	<b>7</b>
<b>8.4</b>	<b>Operational qualification .....</b>	<b>8</b>
<b>8.5</b>	<b>Performance qualification .....</b>	<b>8</b>
<b>8.6</b>	<b>Review and approval of validation .....</b>	<b>10</b>
<b>8.7</b>	<b>Requalification .....</b>	<b>10</b>
<b>9</b>	<b>Routine monitoring and control .....</b>	<b>10</b>
<b>9.1</b>	<b>SIP process control .....</b>	<b>10</b>
<b>9.2</b>	<b>Procedures .....</b>	<b>10</b>
<b>9.3</b>	<b>SIP process records .....</b>	<b>11</b>
<b>9.4</b>	<b>Change control .....</b>	<b>11</b>
<b>9.5</b>	<b>Maintenance of equipment .....</b>	<b>11</b>
<b>10</b>	<b>Personnel training .....</b>	<b>11</b>
	<b>Annex A (informative) Steam sterilization in place .....</b>	<b>12</b>
	<b>Bibliography .....</b>	<b>14</b>