

# ISO 14937:2009-10 (E)

## Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices

---

<b>Contents</b>		<b>Page</b>
Foreword .....		v
Introduction .....		vi
<b>1</b>	<b>Scope .....</b>	<b>1</b>
1.1	Inclusions .....	1
1.2	Exclusions .....	1
<b>2</b>	<b>Normative references .....</b>	<b>2</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>2</b>
<b>4</b>	<b>Quality management system elements .....</b>	<b>7</b>
4.1	Documentation .....	7
4.2	Management responsibility .....	7
4.3	Product realization .....	8
4.4	Measurement, analysis and improvement -- Control of non-conforming product .....	8
<b>5</b>	<b>Sterilizing agent characterization .....</b>	<b>8</b>
5.1	General .....	8
5.2	Sterilizing agent .....	8
5.3	Microbicidal effectiveness .....	8
5.4	Effects on materials .....	9
5.5	Safety and the environment .....	9
<b>6</b>	<b>Process and equipment characterization .....</b>	<b>9</b>
6.1	General .....	9
6.2	Process characterization .....	9
6.3	Equipment characterization .....	10
<b>7</b>	<b>Product definition .....</b>	<b>10</b>
<b>8</b>	<b>Process definition .....</b>	<b>11</b>
<b>9</b>	<b>Validation .....</b>	<b>12</b>
9.1	General .....	12
9.2	Installation qualification .....	12
9.3	Operational qualification .....	13
9.4	Performance qualification .....	13
9.5	Review and approval of validation .....	14
<b>10</b>	<b>Routine monitoring and control .....</b>	<b>14</b>
<b>11</b>	<b>Product release from sterilization .....</b>	<b>14</b>
<b>12</b>	<b>Maintaining process effectiveness .....</b>	<b>15</b>
12.1	General .....	15
12.2	Recalibration .....	15
12.3	Maintenance of equipment .....	15
12.4	Requalification .....	15
12.5	Assessment of change .....	15

<b>Annex A (normative) Factors to be considered in selection of microorganisms for demonstrating microbicidal effectiveness .....</b>	<b>16</b>
<b>Annex B (normative) Approach 1 -- Process definition based on inactivation of the microbial population in its natural state .....</b>	<b>18</b>
<b>Annex C (normative) Approach 2 -- Process definition based on inactivation of reference microorganisms and knowledge of bioburden .....</b>	<b>19</b>
<b>Annex D (normative) Approach 3 -- Conservative process definition based on inactivation of reference microorganisms .....</b>	<b>20</b>
<b>Annex E (informative) Guidance on application of this International Standard .....</b>	<b>22</b>
<b>Bibliography .....</b>	<b>36</b>