

# ISO 20857:2010-08 (E)

## Sterilization of health care products - Dry heat - Requirements for 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>10</b>
4.1	Documentation .....	10
4.2	Management responsibility .....	10
4.3	Product realization .....	10
4.4	Measurement, analysis and improvement -- Control of nonconforming product .....	10
<b>5</b>	<b>Sterilizing agent characterization .....</b>	<b>11</b>
5.1	Sterilizing agent .....	11
5.2	Microbicidal effectiveness .....	11
5.3	Material effects .....	11
5.4	Environmental considerations .....	11
<b>6</b>	<b>Process and equipment characterization .....</b>	<b>11</b>
6.1	Process characterization .....	11
6.2	Equipment characterization .....	11
<b>7</b>	<b>Product definition .....</b>	<b>13</b>
7.1	General .....	13
7.2	Product safety and performance .....	13
7.3	Packaging considerations .....	14
7.4	Microbiological quality .....	14
7.5	Product family .....	14
7.6	Biological safety .....	14
<b>8</b>	<b>Process definition .....</b>	<b>15</b>
<b>9</b>	<b>Validation .....</b>	<b>16</b>
9.1	General .....	16
9.2	Installation qualification .....	16
9.3	Operational qualification .....	16
9.4	Performance qualification .....	16
9.5	Additional sterilization systems .....	18
9.6	Review and approval of validation .....	18
<b>10</b>	<b>Routine monitoring and control .....</b>	<b>19</b>
10.1	Routine control .....	19
10.2	Routine monitoring .....	19
10.3	Process monitoring locations .....	20

11	Product release from sterilization/depyrogenation .....	21
12	Maintaining process effectiveness .....	21
12.1	General .....	21
12.2	Recalibration .....	21
12.3	Maintenance of equipment .....	21
12.4	Requalification .....	21
12.5	Assessment of change .....	22
Annex A (informative) Guidance on the application of this International Standard .....		23
Annex B (informative) Process definition based on inactivation of the microbial population in its natural state (bioburden-based approach) .....		46
Annex C (informative) Process definition based on the inactivation of reference microorganisms and knowledge of bioburden (combined bioburden/biological indicator approach) .....		48
Annex D (informative) Conservative process definition based on inactivation of reference microorganisms (overkill method) .....		51
Annex E (informative) Process development .....		54
Bibliography .....		57