

# ISO 17665:2024-03 (E)

## Sterilization of health care products - Moist 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>General .....</b>	<b>12</b>
<b>5</b>	<b>Sterilizing agent characterization .....</b>	<b>13</b>
5.1	Sterilizing agent .....	13
5.2	Microbicidal effectiveness .....	14
5.3	Effects on materials .....	14
5.4	Environmental consideration .....	14
<b>6</b>	<b>Process and equipment characterization .....</b>	<b>14</b>
6.1	General .....	14
6.2	Process characterization .....	14
6.3	Saturated steam sterilization processes .....	15
6.4	Contained product sterilization processes .....	16
6.5	Equipment .....	17
<b>7</b>	<b>Product definition .....</b>	<b>18</b>
<b>8</b>	<b>Process definition .....</b>	<b>20</b>
<b>9</b>	<b>Validation .....</b>	<b>22</b>
9.1	General .....	22
9.2	Installation qualification (IQ) .....	23
9.3	Operational qualification (OQ) .....	23
9.4	Performance qualification (PQ) .....	24
9.5	Review and approval of validation .....	26
<b>10</b>	<b>Routine monitoring and control .....</b>	<b>26</b>
10.1	Routine monitoring .....	26
10.2	Operational status .....	26
10.3	Process verification .....	27
10.4	Evaluation of additional data for saturated steam sterilization processes .....	27
10.5	Evaluation of additional data for contained product sterilization processes .....	27
10.6	Record retention .....	28
<b>11</b>	<b>Product release from sterilization .....</b>	<b>28</b>
<b>12</b>	<b>Maintaining process effectiveness .....</b>	<b>28</b>

12.1	Purpose .....	28
12.2	Demonstration of continued effectiveness .....	28
12.3	Recalibration .....	29
12.4	Equipment maintenance .....	29
12.5	Requalification .....	29
12.6	Assessment of change .....	30
Annex A	(informative) Guidance on the principles of moist heat sterilization and rationales for requirements .....	31
Annex B	(informative) Establishment and evaluation of a sterilization process primarily based on microbiological inactivation .....	59
Annex C	(informative) Establishment and evaluation of a sterilization process primarily based on the measurement of physical parameters .....	73
ISO 17665:2024(en)	Annex D (informative) Examples of moist heat sterilization cycles .....	83
Annex E	(informative) Temperature and pressure of saturated steam for use in moist heat sterilization .....	89
Annex F	(informative) Guidance on the application of the normative requirements in health care facilities .....	93
Annex G	(informative) Guidance on the designation of a medical device to a product family and processing category for sterilization by moist heat .....	118
Annex H	(informative) Guidance on the application of the normative requirements in industrial settings .....	126
Bibliography	.....	150