

# ISO/TS 17665-3:2013-04 (E)

## Sterilization of health care products - Moist heat - Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization

---

<b>Contents</b>		<b>Page</b>
Foreword .....		iv
Introduction .....		v
<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>1</b>
<b>4</b>	<b>Classification .....</b>	<b>2</b>
<b>4.1</b>	<b>General attributes .....</b>	<b>2</b>
<b>4.2</b>	<b>Detailed attributes .....</b>	<b>2</b>
<b>5</b>	<b>Product family (pf) .....</b>	<b>5</b>
<b>5.1</b>	<b>Example 1 -- pf 1 .....</b>	<b>6</b>
<b>5.2</b>	<b>Example 2 -- pf 24 .....</b>	<b>6</b>
<b>5.3</b>	<b>Example 3 -- pf 27 .....</b>	<b>7</b>
<b>6</b>	<b>Processing category .....</b>	<b>8</b>
<b>7</b>	<b>Sterilization process parameters .....</b>	<b>8</b>
<b>8</b>	<b>Additional considerations .....</b>	<b>8</b>
<b>8.1</b>	<b>Services .....</b>	<b>8</b>
<b>8.2</b>	<b>Process selection .....</b>	<b>9</b>
	<b>Annex A (informative) Process parameters .....</b>	<b>10</b>
	<b>Annex B (informative) Characterization of a procedure set -- Examples .....</b>	<b>13</b>
	<b>Annex C (informative) Designating a processing category .....</b>	<b>29</b>
	<b>Annex D (informative) Processing categories -- Examples .....</b>	<b>31</b>
	<b>Bibliography .....</b>	<b>49</b>