

# DIN EN ISO 11138-1:2006-09 (E)

## Sterilization of health care products - Biological indicators - Part 1: General requirements (ISO 11138-1:2006)

---

<b>Contents</b>		<b>Page</b>
Foreword .....		2
Introduction .....		4
<b>1</b>	<b>Scope .....</b>	<b>5</b>
1.1	General .....	5
1.2	Exclusions .....	5
<b>2</b>	<b>Normative references .....</b>	<b>5</b>
<b>3</b>	<b>Terms and definitions .....</b>	<b>6</b>
<b>4</b>	<b>General manufacturing requirements .....</b>	<b>8</b>
4.1	Manufacturing controls .....	8
4.2	Test organism .....	9
4.3	Information supplied by manufacturer (labelling) .....	10
4.4	Storage and transport .....	10
<b>5</b>	<b>Specific manufacturing requirements .....</b>	<b>11</b>
5.1	Suspensions .....	11
5.2	Carrier, primary and secondary packaging .....	11
5.3	Inoculated carrier .....	12
5.4	Biological indicators .....	12
5.5	Self-contained biological indicators .....	12
<b>6</b>	<b>Determination of resistance .....</b>	<b>12</b>
6.1	General resistance requirements .....	12
6.2	Test organism .....	13
6.3	Population of test organisms .....	13
6.4	Resistance characteristics .....	13
6.5	Test conditions .....	14
<b>7</b>	<b>Culture conditions .....</b>	<b>14</b>
7.1	Incubator .....	14
7.2	Growth medium .....	14
7.3	Incubation .....	14
<b>Annex A (normative)</b>	<b>Determination of viable count .....</b>	<b>15</b>
<b>Annex B (normative)</b>	<b>Determination of growth inhibition by carriers and primary packaging materials exposed to sterilization processes .....</b>	<b>17</b>
<b>Annex C (normative)</b>	<b>D value determination by survivor curve method .....</b>	<b>19</b>
<b>Annex D (normative)</b>	<b>D value determination by fraction negative method .....</b>	<b>23</b>
<b>Annex E (normative)</b>	<b>Survival-kill response characteristics .....</b>	<b>39</b>
<b>Annex F (informative)</b>	<b>Relationship between components of biological indicators .....</b>	<b>40</b>
<b>Bibliography .....</b>		<b>41</b>