

# DIN EN ISO 11138-2:2017-07 (E)

## Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2017)

---

<b>Contents</b>	<b>Page</b>
European foreword .....	3
Foreword .....	4
Introduction .....	5
1 Scope .....	6
2 Normative references .....	6
3 Terms and definitions .....	6
4 General requirements .....	6
5 Test organism .....	6
6 Suspension .....	7
7 Carrier and primary packaging .....	7
8 Inoculated carriers and biological indicators .....	7
9 Population and resistance .....	7
<b>Annex A (normative) Method for determination of resistance to ethylene oxide sterilization .....</b>	<b>9</b>
<b>Annex B (informative) Rationale for the inclusion of a second minimum <i>D</i> value specification as a result of changes to the test gas used to evaluate resistance and deletion of the requirement for a minimum <i>D</i> value at 30 °C .....</b>	<b>10</b>
<b>Bibliography .....</b>	<b>11</b>