

# ISO 11140-1:2005-07 (E)

## Sterilization of health care products - Chemical indicators - Part 1: General requirements

---

<b>Contents</b>	<b>Page</b>
Foreword .....	iv
Introduction .....	v
1 Scope .....	1
2 Normative references .....	1
3 Terms and definitions .....	2
4 Classification .....	3
5 General requirements .....	4
6 Performance requirements .....	6
7 Test methods .....	7
8 Additional requirements for process (Class 1) indicators .....	10
9 Additional requirements for single variable (Class 3) indicators .....	13
10 Additional requirements for multi-variable (Class 4) indicators .....	13
11 Additional requirements for steam integrating (Class 5) indicators .....	14
12 Additional requirements for dry heat integrating (Class 5) indicators .....	14
13 Additional requirements for ethylene oxide integrating (Class 5) indicators .....	15
14 Additional requirements for emulating (Class 6) indicators .....	16
Annex A (informative) Method for demonstrating shelf life of the product .....	17
Annex B (informative) Examples of testing indicators .....	18
Annex C (informative) Rationale for the requirements for integrating indicators and the link to the inactivation .....	19
Annex D (informative) Rationale for the liquid-phase test method for steam-formaldehyde indicators .....	25
Annex E (informative) Relationship of indicator components .....	26
Bibliography .....	27