

# ISO 11140-1:2014-11 (E)

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

---

<b>Contents</b>		<b>Page</b>
Foreword .....		v
Introduction .....		vi
1	Scope .....	1
2	Normative references .....	1
3	Terms and definitions .....	2
4	Categorization .....	4
4.1	General .....	4
4.2	Type 1: process indicators .....	4
4.3	Type 2: indicators for use in specific tests .....	5
4.4	Type 3: single critical process variable indicators .....	5
4.5	Type 4: multicritical process variable indicators .....	5
4.6	Type 5: integrating indicators .....	5
4.7	Type 6: emulating indicators .....	5
5	General requirements .....	5
6	Performance requirements .....	8
6.1	General .....	8
6.2	Type 1 indicators .....	9
6.3	Type 2 indicators .....	9
6.4	Types 3, 4, 5 and 6 indicators .....	9
7	Test methods .....	9
7.1	General .....	9
7.2	Off-set (transference) .....	9
7.3	Procedure -- Steam indicators .....	9
7.4	Procedure -- Dry heat indicators .....	10
7.5	Procedure -- EO indicators .....	10
7.6	Procedure -- Low temperature steam and formaldehyde indicators .....	11
7.7	Procedure -- Vaporized hydrogen peroxide indicators .....	11
8	Additional requirements for process (Type 1) indicators .....	12
8.1	Process indicators printed or applied on to packaging material .....	12
8.2	Process indicators for steam sterilization processes .....	12
8.3	Process indicators for dry heat sterilization processes .....	12
8.4	Process indicators for ethylene oxide sterilization processes .....	13
8.5	Process indicators for radiation sterilization processes .....	13
8.6	Process indicators for low temperature steam and formaldehyde sterilization processes .....	14
8.7	Process indicators for vaporized hydrogen peroxide sterilization processes .....	14
9	Additional requirements for single critical process variable (Type 3) indicators .....	15
10	Additional requirements for multicritical process variable (Type 4) indicators .....	15
11	Additional requirements for steam integrating (Type 5) indicators .....	16

12	Additional requirements for ethylene oxide integrating (Type 5) indicators .....	17
13	Additional requirements for emulating (Type 6) indicators .....	17
	Annex A (normative) Method for demonstrating shelf-life of the product .....	19
	Annex B (informative) Examples of testing indicators .....	20
	Annex C (informative) Rationale for the requirements for integrating indicators and the link to the requirements for biological indicators specified in ISO 11138 (all parts) and microbial inactivation .....	22
	Annex D (informative) Rationale for the liquid-phase test method for low temperature steam and formaldehyde indicators .....	29
	Annex E (informative) Relationship of indicator and indicator system components .....	30
	Bibliography .....	31