

ISO 15882:2008-09 (E)

Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Terms and definitions	1
3	General considerations	3
4	Classes of chemical indicator	5
4.1	General	5
4.2	Class 1: Process indicators	5
4.3	Class 2: Indicators for use in specific tests	6
4.4	Class 3: Single variable indicators	6
4.5	Class 4: Multi-variable indicators	8
4.6	Class 5: Integrating indicators	8
4.7	Class 6: Emulating indicators	9
5	Selection of chemical indicators	10
6	Use of chemical indicators	10
6.1	Class 1 process indicators	10
6.2	Class 2 indicators	11
6.3	Class 3, 4, 5 and 6 indicators	11
6.4	Indicators for use with process challenge devices	11
7	Interpretation of results from chemical indicators	12
7.1	General	12
7.2	Chemical indicator responses	12
7.3	Chemical indicators showing "fail" response	12
8	Chemical indicators in sterility assurance procedures	12
8.1	General	12
8.2	Record keeping	13
9	Personnel training	13
10	Storage and handling	14
11	Labelling	14
11.1	General	14
11.2	Indicator marking	14
11.3	Process marking	14
11.4	Package marking	14
Annex A (informative) Background on the Bowie and Dick test		16
Annex B (informative) Explanation of the terms "parameter" and "variable"		19

Annex C (informative) Rationale for the requirements for integrating indicators and the link to the requirements for biological indicators (BIs) specified in the ISO 11138 series and microbial inactivation (derived from ISO 11140-1)	20
Annex D (informative) Specifications for porosity	27
Annex E (informative) Figure showing relationship of indicator components	29
Bibliography	30