

ISO 11138-1:2017-03 (E)

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

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 General manufacturing requirements	4
4.1 Manufacturing controls	4
4.1.1 Quality management systems	4
4.1.2 Traceability	4
4.1.3 Finished product requirements	4
4.1.4 Personnel	4
4.2 Test organism	4
4.2.1 Strain	4
4.2.2 Originating inoculum for suspension	5
4.2.3 Test organism count	5
4.3 Information to be provided by the manufacturer (labelling)	5
4.4 Storage and transport	6
5 Specific manufacturing requirements	7
5.1 Suspensions	7
5.2 Carrier, primary and secondary packaging	7
5.3 Inoculated carrier	7
5.4 Biological indicators	8
5.5 Self-contained biological indicators	8
6 Determination of population and resistance	8
6.1 General resistance requirements	8
6.2 Test organism	8
6.3 Population of test organisms	8
6.4 Resistance characteristics	9
6.5 Test conditions	9
7 Culture conditions	10
7.1 Incubator	10
7.2 Growth medium	10
7.3 Incubation	10
7.4 Software validation	11
7.5 Incubation time using detection system	11
Annex A (normative) Determination of viable count	12
Annex B (normative) Determination of growth inhibition by carriers and primary packaging materials exposed to sterilization processes	14
Annex C (normative) D value determination by survivor curve method	17

Annex D (normative) D value determination by fraction negative method	21
Annex E (normative) Survival-kill response characteristics	37
Annex F (informative) Relationship between components of biological indicators	39
Bibliography	40