

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