

ISO 11138-1:2006-07 (E)

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

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
1.1	General	1
1.2	Exclusions	1
2	Normative references	1
3	Terms and definitions	2
4	General manufacturing requirements	4
4.1	Manufacturing controls	4
4.2	Test organism	5
4.3	Information supplied by manufacturer (labelling)	6
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	8
5.4	Biological indicators	8
5.5	Self-contained biological indicators	8
6	Determination of resistance	8
6.1	General resistance requirements	8
6.2	Test organism	9
6.3	Population of test organisms	9
6.4	Resistance characteristics	9
6.5	Test conditions	10
7	Culture conditions	10
7.1	Incubator	10
7.2	Growth medium	10
7.3	Incubation	10
Annex A (normative)	Determination of viable count	11
Annex B (normative)	Determination of growth inhibition by carriers and primary packaging materials exposed to sterilization processes	13
Annex C (normative)	D value determination by survivor curve method	15
Annex D (normative)	D value determination by fraction negative method	19
Annex E (normative)	Survival-kill response characteristics	35
Annex F (informative)	Relationship between components of biological indicators	36
Bibliography		37