

DIN EN ISO 11737-1:2018-11 (E)

Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)

Contents	Page
European foreword	4
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices [OJ L 189] aimed to be covered	6
Annex ZB (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices [OJ L 169] aimed to be covered	8
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices [OJ L 331] aimed to be covered	10
Foreword	12
Introduction	14
1 Scope	16
2 Normative references	16
3 Terms and definitions	16
4 General requirements	19
4.1 Documentation	19
4.2 Management responsibility	20
4.3 Product realization	20
4.4 Measurement, analysis and improvement	20
5 Selection of products	20
5.1 General	20
5.2 Sample item portion (SIP)	21
6 Methods of determination and microbial characterization of bioburden	21
6.1 Determination of bioburden	21
6.1.1 Selection of an appropriate method	21
6.1.2 Neutralization of inhibitory substances	22
6.1.3 Removal of microorganisms	22
6.1.4 Culturing of microorganisms	22
6.1.5 Enumeration of microorganisms	22
6.2 Microbial characterization of bioburden	22
7 Validation of the method for determining bioburden	23
7.1 General	23
7.2 Validation	23
8 Routine determination of bioburden and interpretation of data	23
8.1 General	23
8.2 Limits of detection and plate counting	23
8.3 Microbial characterization	23
8.4 Bioburden data for extent of treatment	24
8.5 Bioburden spikes	24
8.6 Bioburden levels	24
8.7 Data analysis	24
8.8 Statistical methods	24

9	Maintenance of the method for determining bioburden	24
9.1	Changes to the product and/or manufacturing process	24
9.2	Changes to the method for determining bioburden	24
9.3	Requalification of the method for determining bioburden	24
	Annex A (informative) Guidance on the determination of a population of microorganisms on products	25
	Annex B (informative) Guidance on methods to determine bioburden	42
	Annex C (informative) Validation of bioburden recovery efficiency	52
	Annex D (informative) Typical assignment of responsibilities	60
	Bibliography	62