

DIN EN ISO 13408-2:2018-06 (E)

Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)

Contents	Page
European foreword.....	4
Endorsement notice.....	5
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.....	7
Annex ZC (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on <i>in vitro</i> diagnostic medical devices [OJ L 331] aimed to be covered.....	8
Foreword.....	9
Introduction.....	10
1 Scope.....	11
2 Normative references.....	11
3 Terms and definitions.....	12
4 Quality system elements.....	13
4.1 General.....	13
4.2 Management responsibility.....	13
4.3 Procurement of filters.....	13
5 Sterilizing filter characterization.....	13
5.1 General.....	13
5.2 Microbial removal effectiveness.....	14
5.3 Material effects.....	14
5.4 Environmental considerations.....	15
6 Process and equipment characterization.....	15
6.1 General.....	15
6.2 Risk management.....	15
6.3 Process characterization.....	16
6.4 Equipment characterization.....	16
7 Fluid definition.....	17
7.1 General.....	17
7.2 Microbiological quality.....	18
8 Process definition.....	18
8.1 General.....	18
8.2 Filter definition and characterization.....	19
8.2.1 General.....	19
8.2.2 Compatibility between the filter and fluid.....	19
8.2.3 Filter use.....	20
8.3 Filtration process definition.....	20
8.4 Integrity testing process definition.....	21

9	Validation	22
9.1	General	22
9.2	Validation of fluid-specific microbial retention by sterilizing filters for liquids	22
9.2.1	General	22
9.2.2	Test organism	23
9.3	Validation of the integrity test for sterilizing filters for liquids	24
9.4	Validation of filter interactions with the process fluid	25
9.5	Validation of the sterilization of filter system	25
9.6	Validation of fluid-specific microbial retention by sterilizing filters for gases	25
9.6.1	General	25
9.6.2	Aerosol retention	25
9.6.3	Validation of physical integrity testing	25
9.6.4	Compatibility and service life	26
9.6.5	Validation of the sterilization of the filter system for gases	26
10	Routine monitoring and control	26
11	Product release from sterilizing filtration	26
12	Maintaining process effectiveness	27
12.1	General	27
12.2	Recalibration	27
12.3	Maintenance of equipment	27
12.4	Requalification	27
12.5	Assessment of change	28
Annex A (informative) Guidance on the application of this document		29
Bibliography		44