

DIN EN ISO 13408-1:2015-12 (E)

Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)

Contents		Page
Foreword		4
Introduction		6
1	Scope	8
2	Normative references	8
3	Terms and definitions	9
4	Quality system elements	14
4.1	General	14
4.2	Assignment of responsibilities	14
4.3	Calibration	14
5	Aseptic process definition	15
5.1	General	15
5.2	Risk management	15
6	Manufacturing environment	17
6.1	General	17
6.2	Manufacturing environment design	18
6.3	Layout	19
6.4	Material and personnel flow	21
6.5	HVAC system	22
6.6	Cleanroom qualification	24
6.7	Utility services and ancillary equipment	24
6.8	Environmental and personnel monitoring programmes	24
7	Equipment	28
7.1	Qualification	28
7.2	Maintenance of equipment	30
8	Personnel	30
8.1	General	30
8.2	Training for APA qualification	31
8.3	Gowning procedures	32
8.4	General employee health	33
9	Manufacture of the product	34
9.1	Attainment and maintenance of sterility	34
9.2	Duration of the manufacturing process	34
9.3	Aseptic manufacturing procedures	35
9.4	Cleaning and disinfection of facilities	35
9.5	Cleaning, disinfection and sterilization of equipment	37
10	Process simulation	38
10.1	General	38
10.2	Media selection and growth support	39
10.3	Simulation procedures	39
10.4	Incubation and inspection of media filled units	40

10.5	Initial performance qualification	40
10.6	Periodic performance requalification	41
10.7	Repeat of initial performance qualification	42
10.8	Documentation of process simulations	42
10.9	Disposition of filled product	43
11	Test for sterility	44
11.1	General	44
11.2	Investigation of positive units from tests for sterility	44
Annex A (informative)	Example of a flow chart	45
Annex B (informative)	Typical elements of an aseptic process definition	46
Annex C (informative)	Examples of specific risks	47
Annex D (informative)	Comparison of classification of cleanrooms	48
Annex E (informative)	Specification for water used in the process	49
Annex F (informative)	Aseptic processing area	51
Bibliography	56
Annex ZA (informative)	Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices	52
Annex ZB (informative)	Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices	53
Annex ZC (informative)	Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices	54