

DIN EN ISO 11135:2020-04 (E)

Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014 + Amd.1:2018) (includes Amendment :2019)

Contents	Page
European foreword	4
Ⓐ1 European foreword to Amendment 1 Ⓐ1	5
Ⓐ1 Foreword to Amendment 1 Ⓐ1	7
Introduction	8
1 Scope	10
1.1 Inclusions.....	10
1.2 Exclusions.....	10
2 Normative references	11
3 Terms and definitions	12
4 Quality management systems	20
4.1 Documentation	20
4.2 Management responsibility	20
4.3 Product realization.....	20
4.4 Measurement, analysis and improvement — Control of nonconforming product	20
5 Sterilizing agent characterization	20
5.1 General.....	20
5.2 Sterilizing agent	21
5.3 Microbicidal effectiveness.....	21
5.4 Material effects.....	21
5.5 Safety and the environment.....	21
6 Process and equipment characterization	21
6.1 General.....	21
6.2 Process characterization	21
6.3 Equipment characterization.....	22
7 Product definition	23
7.1 General.....	23
7.2 Product safety, quality and performance	24
7.3 Microbiological quality	24
7.4 Documentation	24
8 Process definition	24
9 Validation	25
9.1 General.....	25
9.2 Installation qualification, IQ.....	26
9.3 Operational qualification, OQ.....	26
9.4 Performance qualification, PQ.....	27
9.5 Review and approval of validation	29
10 Routine monitoring and control	31
11 Product release from sterilization	32
12 Maintaining process effectiveness	32

12.1	General.....	32
12.2	Maintenance of equipment.....	33
12.3	Requalification.....	33
12.4	Assessment of change.....	33
12.5	Assessment of equivalence.....	34
Annex A (normative) Determination of lethal rate of the sterilization process — Biological indicator/bioburden approach.....		
		35
Annex B (normative) Conservative determination of lethal rate of the sterilization process — Overkill approach.....		
		36
Annex C (informative) Temperature sensors, RH sensors and biological indicator numbers.....		
		38
Annex D (informative) Guidance on the application of the normative requirements.....		
		41
Ⓐ	Annex E (normative) Single batch release[Ⓐ].....	83
Ⓐ	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[Ⓐ].....	86
Ⓐ	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 [Ⓐ].....	88
Ⓐ	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[Ⓐ].....	90
Ⓐ	Annex ZD (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered [Ⓐ].....	92
Ⓐ	Annex ZE (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered [Ⓐ].....	95
Bibliography.....		97