

DIN EN ISO 11135:2014-10 (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)

Contents	Page
Foreword	4
Introduction	5
1 Scope	7
1.1 Inclusions	7
1.2 Exclusions	7
2 Normative references	8
3 Terms and definitions	9
4 Quality management systems	17
4.1 Documentation	17
4.2 Management responsibility	17
4.3 Product realization	17
4.4 Measurement, analysis and improvement -- Control of nonconforming product	17
5 Sterilizing agent characterization	17
5.1 General	17
5.2 Sterilizing agent	18
5.3 Microbicidal effectiveness	18
5.4 Material effects	18
5.5 Safety and the environment	18
6 Process and equipment characterization	18
6.1 General	18
6.2 Process characterization	18
6.3 Equipment characterization	19
7 Product definition	20
7.1 General	20
7.2 Product safety, quality and performance	21
7.3 Microbiological quality	21
7.4 Documentation	21
8 Process definition	21
9 Validation	22
9.1 General	22
9.2 Installation qualification, IQ	23
9.3 Operational qualification, OQ	23
9.4 Performance qualification, PQ	24
9.5 Review and approval of validation	26
10 Routine monitoring and control	28
11 Product release from sterilization	29

12	Maintaining process effectiveness	29
12.1	General	29
12.2	Maintenance of equipment	30
12.3	Requalification	30
12.4	Assessment of change	30
12.5	Assessment of equivalence	31
Annex A (normative)	Determination of lethal rate of the sterilization process -- Biological indicator/bioburden approach	32
Annex B (normative)	Conservative determination of lethal rate of the sterilization process -- Overkill approach	33
Annex C (informative)	Temperature sensors, RH sensors and biological indicator numbers	35
Annex D (informative)	Guidance on the application of the normative requirements	38
Annex E (normative)	Single Lot Release	80
Annex ZA (informative)	Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC	82
Annex ZB (informative)	Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC	83
Bibliography		90