

ISO 11135:2014-07 (E)

Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
1.1	Inclusions	1
1.2	Exclusions	1
2	Normative references	2
3	Terms and definitions	3
4	Quality management systems	11
4.1	Documentation	11
4.2	Management responsibility	11
4.3	Product realization	11
4.4	Measurement, analysis and improvement -- Control of nonconforming product	11
5	Sterilizing agent characterization	11
5.1	General	11
5.2	Sterilizing agent	12
5.3	Microbicidal effectiveness	12
5.4	Material effects	12
5.5	Safety and the environment	12
6	Process and equipment characterization	12
6.1	General	12
6.2	Process characterization	12
6.3	Equipment characterization	13
7	Product definition	14
7.1	General	14
7.2	Product safety, quality and performance	15
7.3	Microbiological quality	15
7.4	Documentation	15
8	Process definition	15
9	Validation	16
9.1	General	16
9.2	Installation qualification, IQ	17
9.3	Operational qualification, OQ	17
9.4	Performance qualification, PQ	18
9.5	Review and approval of validation	20
10	Routine monitoring and control	22
11	Product release from sterilization	23

12	Maintaining process effectiveness	23
12.1	General	23
12.2	Maintenance of equipment	24
12.3	Requalification	24
12.4	Assessment of change	24
12.5	Assessment of equivalence	25
Annex A (normative)	Determination of lethal rate of the sterilization process -- Biological indicator/bioburden approach	26
Annex B (normative)	Conservative determination of lethal rate of the sterilization process -- Overkill approach	27
Annex C (informative)	Temperature sensors, RH sensors and biological indicator numbers	29
Annex D (informative)	Guidance on the application of the normative requirements	32
Annex E (normative)	Single Lot Release	74
Bibliography		76