

ISO/TS 17665-2:2009-01 (E)

Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	2
4	Quality management system elements	2
5	Sterilizing agent characterization	2
5.1	Sterilizing agent	2
5.2	Microbicidal effectiveness	2
5.3	Material effects	3
5.4	Environmental considerations	3
6	Process and equipment characterization	3
6.1	Process	3
6.2	Equipment	6
7	Product definition	7
8	Process definition	8
9	Validation	10
9.1	General	10
9.2	Installation qualification (IQ)	11
9.3	Operational qualification (OQ)	11
9.4	Performance qualification (PQ)	13
9.5	Review and approval of the validation	14
10	Routine monitoring and control	15
11	Product release from sterilization	16
12	Maintaining process effectiveness	17
12.1	Demonstration of continued effectiveness	17
12.2	Recalibration	17
12.3	Maintenance of equipment	17
12.4	Requalification	17
12.5	Assessment of change	18
Annex A (informative)	Evaluation of a sterilization process primarily based on the measurement of physical parameters	19
Annex B (informative)	Evaluation of a sterilization process primarily based on biological inactivation and an accompanying mechanical air removal procedure	27
Annex C (informative)	Temperature and pressure of saturated steam for use in moist heat sterilization	30

Annex D (informative) Special considerations for health care settings	32
Annex E (informative) Index of normative clauses/subclauses of ISO 17665-1 and cited references or related guidance given in ISO 17665-1 and ISO/TS 17665-2	41
Bibliography	44