

DIN EN ISO 17665:2024-09 (E)

Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)

Contents	Page
European foreword	4
Annex ZA (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered	5
Annex ZB (informative) Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered	10
Foreword	13
Introduction	14
1 Scope	16
1.1 Inclusions.....	16
1.2 Exclusions.....	16
2 Normative references	17
3 Terms and definitions	17
4 General	27
5 Sterilizing agent characterization	28
5.1 Sterilizing agent.....	28
5.2 Microbicidal effectiveness.....	29
5.3 Effects on materials.....	29
5.4 Environmental consideration.....	29
6 Process and equipment characterization	29
6.1 General.....	29
6.2 Process characterization.....	29
6.3 Saturated steam sterilization processes.....	30
6.4 Contained product sterilization processes.....	31
6.5 Equipment.....	32
7 Product definition	33
8 Process definition	35
9 Validation	37
9.1 General.....	37
9.2 Installation qualification (IQ).....	38
9.3 Operational qualification (OQ).....	38
9.4 Performance qualification (PQ).....	39
9.5 Review and approval of validation.....	41
10 Routine monitoring and control	41
10.1 Routine monitoring.....	41
10.2 Operational status.....	41
10.3 Process verification.....	42
10.4 Evaluation of additional data for saturated steam sterilization processes.....	42
10.5 Evaluation of additional data for contained product sterilization processes.....	42
10.6 Record retention.....	43
11 Product release from sterilization	43

12	Maintaining process effectiveness	43
12.1	Purpose	43
12.2	Demonstration of continued effectiveness	43
12.3	Recalibration	44
12.4	Equipment maintenance	44
12.5	Requalification	44
12.6	Assessment of change	45
Annex A (informative)	Guidance on the principles of moist heat sterilization and rationales for requirements	46
Annex B (informative)	Establishment and evaluation of a sterilization process primarily based on microbiological inactivation	74
Annex C (informative)	Establishment and evaluation of a sterilization process primarily based on the measurement of physical parameters	88
Annex D (informative)	Examples of moist heat sterilization cycles	98
Annex E (informative)	Temperature and pressure of saturated steam for use in moist heat sterilization	104
Annex F (informative)	Guidance on the application of the normative requirements in health care facilities	108
Annex G (informative)	Guidance on the designation of a medical device to a product family and processing category for sterilization by moist heat	133
Annex H (informative)	Guidance on the application of the normative requirements in industrial settings	141
Bibliography		165