

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 |