ISO 17665:2024-03 (E)

Sterilization of health care products - Moist heat - 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 Termsanddefinitions 2

4 General 12

5 Sterilizing agent characterization 13
5.1 Sterilizing agent 13
5.2 Microbicidal effectiveness 14
5.3 Effects on materials 14
5.4 Environmental consideration 14

6 Process and equipment characterization 14
6.1 General 14
6.2 Process characterization 14
6.3 Saturated steam sterilization processes 15
6.4 Contained product sterilization processes 16
6.5 Equipment 17

7 Productdefinition 18

8 Processdefinition 20

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 26
10.1 Routine monitoring 26
10.2 Operational status 26
10.3 Process verification 27
10.4 Evaluation of additional data for saturated steam sterilization processes 27
10.5 Evaluation of additional data for contained product sterilization processes 27
10.6 Record retention 28

11 Product release from sterilization 28

12 Maintaining process effectiveness 28

12.1 Purpose 28
12.2 Demonstration of continued effectiveness 28
12.3 Recalibration 29
12.4 Equipment maintenance 29
12.5 Requalification 29
12.6 Assessment of change 30

Annex A (informative) Guidance on the principles of moist heat sterilization and rationales for requirements 31

Annex B (informative) Establishment and evaluation of a sterilization process primarily based on microbiological inactivation 59

Annex C (informative) Establishment and evaluation of a sterilization process primarily based on the measurement of physical parameters 73

ISO 17665:2024(en) Annex D (informative) Examples of moist heat sterilization cycles 83

Annex E (informative) Temperature and pressure of saturated steam for use in moist heat sterilization 89

Annex F (informative) Guidance on the application of the normative requirements in health care facilities 93

Annex G (informative) Guidance on the designation of a medical device to a product family and processing category for sterilization by moist heat 118

Annex H (informative) Guidance on the application of the normative requirements in industrial settings 126

Bibliography 150