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Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 2

3 Terms and definitions 2

4 Quality management systems 9
4.1 Documentation 9
4.2 Management responsibility 9
4.3 Product realization 9
4.4 Measurement, analysis and improvement -- Control of nonconforming product 10

5 Sterilizing agent characterization 10
5.1 Sterilizing agent 10
5.2 Microbicidal effectiveness 10
5.3 Material effects 10
5.4 Environmental considerations 10

6 Process and equipment characterization 10
6.1 Process characterization 10
6.2 Equipment characterization 11

7 Product definition 12
7.1 General 12
7.2 Product safety and performance 12
7.3 Microbiological quality 12
7.4 Documentation 13

8 Process definition 13

9 Validation 14
9.1 Installation qualification 14
9.2 Operational qualification 14
9.3 Performance qualification 14
9.4 Varying load configurations 16
9.5 Review and approval of validation 16

10 Routine monitoring and control 18

11 Product release from sterilization 19

12 Maintaining process effectiveness 19
12.1 General 19
12.2 Maintenance of equipment 19
12.3 Requalification 19

12.4 Assessment of change 20

Annex A (normative) Determination of lethal rate of the sterilization process -- Biological indicator/bioburden approach 21

Annex B (normative) Conservative determination of lethal rate of the sterilization process -- Overkill approach 23

Annex C (informative) General guidance 25

Bibliography 41