ISO 14160:2011-07 (E)

Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and rou tine 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 system elements 5
4.1 Documentation 5
4.2 Management responsibility 6
4.3 Product realization 6
4.4 Measurement, analysis and improvement -- Control of non-conforming products 6

5 Sterilizing agent characterization 6
5.1 General 6
5.2 Sterilizing agent 6
5.3 Microbicidal effectiveness 7
5.4 Effects on materials 7
5.5 Safety and the environment 7

6 Process and equipment characterization 7
6.1 General 7
6.2 Process characterization 8
6.3 Equipment characterization 8

7 Product definition 8

8 Process definition 9
8.1 Purpose 9
8.2 Determination of the inactivation kinetics 9
8.3 Method for neutralization 10
8.4 Safety quality and performance 10

9 Validation 10
9.1 General 10
9.2 Installation qualification 11
9.3 Operational qualification 11
9.4 Performance qualification 11
9.5 Review and approval of validation 13

10 Routine monitoring and control 14

11 Product release from sterilization 16

12 Maintaining process effectiveness 16

12.1 General 16
12.2 Maintenance of equipment 16
12.3 Requalification 16
12.4 Assessment of change 17

Annex A (informative) Guidance for the application of this International Standard 18

Annex B (normative) Determination of lethal rate of the sterilization process 29

Annex C (informative) Flowchart for microbicidal effectiveness (see 5.3), process definition (see Clause 8), and microbiological performance qualification (see 9.4.2) 33

Bibliography 34