DIN EN ISO 14160:2011-10 (E)

Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, develop ment, validation and routine control of a sterilization process for medical devices (ISO 14160:2011)

Contents

Page

Foreword 3

Introduction 4

1 Scope 6

2 Normative references 7

3 Terms and definitions 7

4 Quality management system elements 10
4.1 Documentation 10
4.2 Management responsibility 11
4.3 Product realization 11
4.4 Measurement, analysis and improvement -- Control of non-conforming products 11

5 Sterilizing agent characterization 11
5.1 General 11
5.2 Sterilizing agent 11
5.3 Microbicidal effectiveness 12
5.4 Effects on materials 12
5.5 Safety and the environment 12

6 Process and equipment characterization 12
6.1 General 12
6.2 Process characterization 13
6.3 Equipment characterization 13

7 Product definition 13

8 Process definition 14
8.1 Purpose 14
8.2 Determination of the inactivation kinetics 14
8.3 Method for neutralization 15
8.4 Safety quality and performance 15

9 Validation 15
9.1 General 15
9.2 Installation qualification 16
9.3 Operational qualification 16
9.4 Performance qualification 16
9.5 Review and approval of validation 18

10 Routine monitoring and control 19

11 Product release from sterilization 21

12 Maintaining process effectiveness 21

12.1 General 21
12.2 Maintenance of equipment 21
12.3 Requalification 21
12.4 Assessment of change 22

Annex A (informative) Guidance for the application of this International Standard 23

Annex B (normative) Determination of lethal rate of the sterilization process 34

Annex C (informative) Flowchart for microbicidal effectiveness (see 5.3), process definition (see Clause 8), and microbiological performance qualification (see 9.4.2) 38

Bibliography 39

Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 93/42 EEC on Medical Devices 40