

ISO 14160:2020 (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 routine control of a sterilization process for medical devices

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General
5	Sterilizing agent characterization
5.1	General
5.2	Sterilizing agent
5.3	Microbicidal effectiveness
5.4	Effects on materials
5.5	Safety and the environment
6	Process and equipment characterization
6.1	General
6.2	Process characterization
6.3	Equipment characterization
7	Product definition
8	Process definition
8.1	Purpose
8.2	Determination of the inactivation kinetics
8.3	Method for neutralization
8.4	Safety quality and performance
9	Validation
9.1	General
9.2	Installation qualification
9.2.1	Equipment
9.2.2	Installation
9.3	Operational qualification
9.4	Performance qualification
9.4.1	General
9.4.2	Microbiological performance qualification (MPQ)
9.4.2.1	General
9.4.2.2	Combined reference organism/bioburden approach
9.4.2.3	Overkill approach
9.4.3	Physical performance qualification
9.4.4	Aseptic processing qualification
9.5	Review and approval of validation
10	Routine monitoring and control

11 Product release from sterilization

12 Maintaining process effectiveness

- 12.1 General
- 12.2 Maintenance of equipment
- 12.3 Requalification
- 12.4 Assessment of change

Annex A (informative) Guidance for the application of this document

- A.1 Scope
- A.2 Normative references
- A.3 Terms and definitions
- A.4 General
 - A.4.1 Documentation
- A.5 Sterilizing agent characterization
- A.6 Process and equipment characterization
- A.7 Product definition
- A.8 Process definition
- A.9 Validation
- A.10 Routine monitoring and control
- A.11 Product release from sterilization
- A.12 Maintaining process effectiveness

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

- B.1 Combined reference organism/bioburden approach
 - B.1.1 Principle
 - B.1.2 Procedure
 - B.1.3 Process lethality determination
 - B.1.3.1 Direct enumeration (inactivation curve)
 - B.1.3.2 Fraction negative method using the Holcomb-Spearman-Karber procedure (HSKP)
 - B.1.3.3 Fraction negative method using the Stumbo-Murphy-Cochran procedure (SMCP)
- B.2 Overkill approach
 - B.2.1 Principle
 - B.2.2 Procedure

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

Page count: 37