

# ISO 11138-7:2019 (E)

## Sterilization of health care products — Biological indicators — Part 7: Guidance for the selection, use and interpretation of results

---

### Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General
5	Characteristics of biological indicators
5.1	General
5.2	Test organism suspension for direct inoculation of products
5.3	Inoculated carriers
5.4	Self-contained biological indicators
6	Selection of supplier
6.1	General
6.2	Documentation
6.2.1	General
6.2.2	Manufacturer audit
7	Biological indicators in process development
7.1	General
7.2	Overkill approach
7.3	Combined biological indicator and bioburden method
7.4	Bioburden method
8	Biological indicators in sterilization validation
8.1	General
8.2	Placement and handling of biological indicators
8.3	Sterilizer qualification
8.4	Performance qualification
8.5	Review and approval of validation
8.6	Requalification
9	Biological indicators in routine monitoring
9.1	General
9.2	Placement and handling of biological indicators
9.3	Process challenge device
10	Interpretation and acceptance criteria
10.1	General
10.2	Interpretation of results
11	Application of biological indicator standards
11.1	General assessment of biological indicator performance by the user
11.2	Nominal population of test organism
11.3	Resistance determination
11.3.1	General
11.3.2	Survivor curve method

- 11.3.3 Fraction-negative method
- 11.3.4 Survival-kill response characteristics
- 11.4 z value determination
  - 11.4.1 General
  - 11.4.2 Graphically plotting the z value
  - 11.4.3 Mathematically calculating the z value
  - 11.4.4 Correlation coefficient, r, for the z value
- 11.5 F(T, z) equivalent sterilization value determination
- 11.6 Establishing spore-log-reduction
- 11.7 Sterility assurance level calculation
- 11.8 Test equipment
- 12 Culture conditions
  - 12.1 General
  - 12.2 Incubation temperature
  - 12.3 Incubation period
  - 12.4 Choice of growth medium
- 13 Third-party considerations
  - 13.1 General
  - 13.2 Minimum requirements from ISO 11138-1 for replicates and total number of biological indicators
  - 13.3 Test equipment
- 14 Personnel training
- 15 Storage and handling
- 16 Disposal of biological indicators
- Annex A (informative) Microbiological inactivation kinetics and enumeration techniques
- Annex B (informative) Process challenge devices
  - B.1 General
  - B.2 Helices
  - B.3 Standard test packs
  - B.4 User's process challenge devices
  - B.5 Biological test packs
- Annex C (informative) Formulae for D value determination by fraction-negative method
  - C.1 Principles
  - C.2 Materials
  - C.3 Procedure
    - C.3.1 Holcomb-Spearman-Karber Procedure (HSKP)
      - C.3.1.1 Procedure
      - C.3.1.2 Calculations using the HSKP
      - C.3.1.3 Example calculations using the HSKP
    - C.3.2 Limited Holcomb-Spearman-Karber Procedure (LHSKP)
      - C.3.2.1 Calculations using the LHSKP
      - C.3.2.2 Example calculations using the LHSKP
    - C.3.3 Stumbo-Murphy-Cochran Procedure (SMCP)
      - C.3.3.1 Procedure
      - C.3.3.2 Calculations using the SMCP
      - C.3.3.3 Example calculations using the SMCP
- Annex D (informative) Examples of documentation for biological indicators prepared by the user
  - D.1 General
    - D.1.1 Sources of microorganisms
    - D.1.2 Documentation
  - D.2 Commercially available suspension
  - D.3 Suspension from a commercially available strain
  - D.4 Suspension from in-house isolates
  - D.5 Inoculated carriers
    - D.5.1 General

- D.5.2 Documentation of fluid carrier materials
- D.5.3 Documentation of solid carrier materials
- D.5.4 Documentation of inoculated carriers used for D value determinations

**Annex E (informative) Calculation of z value**

**Annex F (informative) D value determination by survivor curve method**

- F.1 Principle
- F.2 Materials
- F.3 Procedure

**Annex G (informative) Survival-kill response characteristics**

- G.1 Principle
- G.2 Materials
- G.3 Procedure

**Page count: 65**