



**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

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**Sterilization of health care products - Microbiological methods -
Part 2: Tests of sterility performed in the definition, validation
and maintenance of a sterilization process**

医疗产品灭菌 微生物学方法 第2部分:用于灭菌过程的定义、确认
(English Translation)

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Table of Contents

Foreword	3
Introduction	5
1 Scope	7
2 Normative references	7
3 Terms and definitions	7
4 General requirements	11
5 Selection of product	12
6 Method for performing tests of sterility	14
7 Assessment of the method for performing tests of sterility	15
8 Maintenance of the method for performing tests of sterility maintenance of a sterilization process	16
Appendix B (Informative) Typical allocation of responsibilities	25
Bibliography	26

1 Scope

1.1

This document specifies the general criteria for tests of sterility on medical devices that have been exposed to a treatment with the sterilizing agent at levels lower than those normally used in sterilization processes. This document is applicable to the definition, validation or maintenance of a sterilization process.

1.2

This document is not applicable to:

- a) test for sterility of sterilized products prior to routine release;
- b) implementation of test for sterility (see 3.12);

Note 1: ISO 11135, ISO 11137-1, ISO 11137-2, ISO 14160, ISO 14937, ISO 17665-

1 and ISO 20857 do not require the performance of tests referred to in a) or b).

- c) test for sterility or test of sterility for demonstration of product shelf life, stability and/or package integrity;

- d) culturing of biological indicators or inoculated products.

Note 2: ISO 11138-7 provides guidance on culturing biological indicators.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

3.10

sample item portion; SIP

Specified part of a health care product, which is used for testing.

[Source: ISO 11139:2018, 3.240, modified]

3.11

sterile

Free from viable microorganisms.

[Source: ISO 11139:2018, 3.271]

3.12

test for sterility

Technical operation performed on the product according to the pharmacopoeia regulations after the product has been aseptically processed or sterilized.

[Source: ISO 11139:2018, 3.298]

3.13

test of sterility

A technical operation required during development, validation or requalification to determine whether a product or its fraction contains viable microorganisms.

Note: This test is performed after treatment with the sterilizing agent at a level lower than that of the complete sterilization process.

[Source: ISO 11139:2018, 3.299, modified]

4 General requirements

4.1

The development, validation, and routine control of a sterilization process is a critical element in product realization of health care products. To ensure consistent implementation of the requirements specified in this document, the necessary processes need to be established, implemented and maintained (see Appendix B). Procedures of particular importance in relation to the development, validation, and routine control of a sterilization process include, but are not limited to:

- control of documentation, including related records;
- assignment of management responsibilities;
- reasonable resource supply, including competent human resources and infrastructure;
- control of externally supplied products;
- identification and traceability of products throughout the process;
- control of non-conforming products.

Note: For regulatory purposes, ISO 13485 covers all stages of the medical device life cycle in terms of quality management systems. Depending on the supply requirements of health care products under relevant regulations, it may be required to implement a complete quality management system and have it assessed by a recognized conformity assessment body.

4.2

A calibration procedure for all equipment, including test instruments, shall be established to meet the requirements of this document.

5.1 General requirements

5.1.1

The procedures for selection and handling of samples for tests of sterility shall ensure that the samples selected are representative of routine production, including packaging materials and all production processes (see 5.3).

5.1.2

During the development, validation and routine control of the sterilization process, if it is necessary to classify one or more products into a product family for tests of sterility, the rationale for inclusion of a product within a product family shall be recorded. The rationale shall include selection criteria to ensure that the products selected from a product family for testing are representative of the whole product family.

5.1.3

The rationale for the number of product items that are selected and the number of batches from which this selection is made shall be documented.

Note: The above information can be found in the standards related to the validation and routine control requirements of the sterilization process.

5.2 Sample item portion

5.2.1

Where applicable, the test of sterility shall be performed on the entire product.

However, if the applicable sterilization standard permits, a selected portion of the product (sample item portion) may be used instead of the entire product in the test of sterility.