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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 18280.1-2025

Sterilization of health care products - Radiation - Part 1: Requirements for the development

医疗产品灭菌 辐射 第1部分：医疗器械灭菌过程的开发、确认和常规控制要求

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Standardization Administration of the PRC

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Foreword

This document was issued on 2 December 2025 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 January 2029.

It is a GB standard without the /T suffix: compliance is mandatory in China.

The document runs to 25 pages in translation. The identification, the dates, the table of contents and the clauses reproduced on this page are taken from the standard itself.

GB 18280.1-2025 Sterilization of health care products - Radiation - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices

1 Scope

GB 18280.1 is the Chinese standard governing radiation sterilization of medical devices: the development, validation and routine control of the process. It applies to irradiators using cobalt-60 or caesium-137, an electron beam from an accelerator, or X-rays from a

generator, and it is the text a manufacturer follows to prove that a sterilizing dose actually sterilizes and that it keeps doing so batch after batch. The clauses run from the characterization of the sterilizing agent and of the process and equipment, through product definition and process definition, to validation, routine monitoring and control, product release from sterilization and maintaining process effectiveness. The document is explicit about what it does not cover: inactivating viruses or the agents of spongiform encephalopathies, designating a device as sterile, a full quality management system, biological indicators, and occupational radiation safety. It is aligned with ISO 11137-1. For anyone sterilizing devices for the Chinese market, this is the standard an inspection works from.

1.1 This document specifies requirements for the development, validation and routine control of a radiation sterilization process for medical devices.

This document is applicable to irradiators using the following radiation sources:

a) The radionuclide 60Co or 137Cs;

b) A electron beam from an electron accelerator;

c) X-rays from an X-ray generator.

1.2 This document is not applicable to sterilization processes for inactivating viruses or the causative agents of spongiform encephalopathies, such as scrapie, bovine spongiform encephalopathy and Creutzfeldt-Jakob disease.

Note: For information on such processes, see GB/T 44353.1, GB/T 44353.2, YY/T 0771.3, ISO 13022 and ICH Q5A.

1.2.1 This document does not specify requirements for designating a medical device as sterile.

Note: For requirements designating medical devices as "sterile" in China, see YY/T 0615.1.

1.2.2 This document does not specify a quality management system for the control of all stages of production of medical devices.

Note: It is not a requirement of this document to have a complete quality management system during manufacture, but the elements of a quality management system that are necessary to control the sterilization process are normatively referenced in appropriate provisions in this document (see Clause 4). Refer to the application of the standards for quality management systems (see GB/T 42061) throughout all stages of production of medical devices, including the sterilization process.

1.2.3 This document does not require that biological indicators be used for validation or monitoring of radiation sterilization, nor does it require that a pharmacopoeial test for sterility be carried out for product release.

1.2.4 This document does not specify requirements for occupational safety associated with the design and operation of irradiation facilities.

Note: For China's regulations on occupational safety related to radiation, see GB 10252, GB 18871 and HJ 979.

1.2.5 This document does not specify requirements for the sterilization of used or reprocessed medical devices.

2 Normative references

The following documents contain provisions which, through reference in this text, constitute provisions of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 19973.1 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (GB/T 19973.1-2023, ISO 11737-1:2018, IDT)

GB/T 19973.2 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (GB/T 19973.2-2025, ISO 11737-2:2019, IDT)

3 Terms and definitions

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

3.1

dose

absorbed dose

quantity of ionizing radiation energy imparted per unit mass of a specified material

Note: The unit of absorbed dose is the gray (Gy), where 1 Gy=1 J/kg (=100 rad).

[Source: ISO 11139:2018, 3.3, modified]

3.2

bioburden

population of viable microorganisms on or in a product and/or sterile barrier system

[Source: ISO 11139:2018, 3.23]

3.3

biological indicator

test system containing viable microorganisms providing a specified resistance to a specified sterilization process

[Source: ISO 11139:2018, 3.29]

3.4

calibration