

ICS 11.080.01
CCS C47



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

GB/T 18280.3-2025

Replacing GB/T 18280.3-2015

**Sterilization of health care products - Radiation - Part 3:
Guidance on dosimetric aspects of development, validation and
routine control**

医疗产品灭菌 辐射 第3部分：开发、确认和常规控制的剂量测量指南
(English Translation)

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Foreword

GB/T 18280.3-2025 is a recommended national standard (GB/T) of the People's Republic of China, issued on 2 December 2025 by the State Administration for Market Regulation and the Standardization Administration of China, with effect from 1 July 2027.

This edition replaces GB/T 18280.3-2015.

The document adopts an international standard (ISO or IEC).

It is under the responsibility of the National Medical Products Administration.

Classification: ICS 11.080.01; CCS C47.

1 Scope

Radiation sterilization of medical products relies on measuring absorbed dose reliably. This document gives guidance on the dosimetric aspects of developing, validating and routinely controlling a radiation sterilization process for medical devices. It supports the requirements set out in the first two parts of the series and in the related international standard, and it is a guidance-oriented recommended national standard.

The scope notes that the guidance is aimed at medical devices, although the dose measurement guidance may also be applied to other products. Sterilization service providers, device manufacturers, dosimetry laboratories and quality and regulatory staff who manage radiation sterilization are the main users.

It was issued on 2 December 2025 and takes effect on 1 July 2027, replacing GB/T 18280.3-2015. The long lead time gives organisations room to review their dosimetry procedures against the new text.