

ICS 11.080.01
CCS C47



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

GB/T 18282.1-2025

Replacing GB 18282.1-2015

**Sterilization of health care products - Chemical indicators - Part
1: General requirements**

医疗保健产品灭菌 化学指示物 第1部分：通则

(English Translation)

Issued on: January 24, 2025

Implemented on: February 1, 2026

**Issued by: State Administration for Market Regulation;
Standardization Administration of China**

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Foreword

GB/T 18282.1-2025 is a recommended national standard (GB/T) of the People's Republic of China, issued on 24 January 2025 by the State Administration for Market Regulation and the Standardization Administration of China, with effect from 1 February 2026.

This edition replaces GB 18282.1-2015.

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

Chemical indicators are used in sterilization processes to show whether a load has been exposed to the process conditions. This document is Part 1 of the series on chemical indicators for the sterilization of health care products and covers the general requirements that apply across indicator types.

Its readers include manufacturers of sterilization indicators, producers of sterile medical devices, hospital central sterile services departments, contract sterilizers and test laboratories. Regulatory staff preparing registration dossiers for medical devices and sterilization consumables may also cite it.

The standard was issued on 24 January 2025 and takes effect on 1 February 2026. It replaces GB 18282.1-2015, and the change in prefix shows that the earlier edition carried the GB designation, while this new edition is a recommended national standard (GB/T). That means it is voluntary on its own, unless made binding by a regulation, product registration requirement or contract. Users of the 2015 edition should review how it is cited in their documentation.