

ICS 11.040.20
CCS C 31



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

GB/T 46388.2-2025

**Sharps injury protection - Requirements and test methods -
Part 2: Reusable sharps containers**

锐器伤害保护 要求和试验方法 第2部分：可重复使用锐器容器
(English Translation)

Issued on: October 5, 2025

Implemented on: November 1, 2026

Issued by: State Administration for Market Regulation

Table of Contents

Preface	
Introduction	
1 Scope	
2 Normative References	
3 Terms and Definitions	
4 Requirements and Suggestions	
4.1 General Rules	
4.2 Design and Configuration	
4.3 Enclosure device	
4.4 Monitoring of Reusable Use	
4.5 Cleaning and Stain Removal	
5 Lifespan simulation before testing	
5.1 General Rules	
5.2 State Adjustment	
5.3 Tilting Simulation with Sharp Objects	
5.4 Transportation Simulation	
5.5 Processing Simulation	
6 Test Methods	
6.1 Stability of sharps containers	
6.2 Handle strength	
6.3 Puncture resistance	
6.4 Resistance to drop damage or leakage	
6.5 Resistance to damage or leakage after tipping over	
7 Quality Monitoring. Quality Assurance After Decontamination	
8 Labels, markings, and instructions for use	
8.1 Labeling and Marking	
8.2 Instructions for Use	
Appendix A (Informative) Microbiological Confirmation	
A.1 Overview	
A.2 4-Log Challenge. Surface Sampling Confirmation of Suspension	
A.3 Microbiological validation of the decontamination process	
Reference	

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 2 of GB/T 46388, "Requirements and Test Methods for Protection Against Sharp Instrument Injuries". GB/T 46388 has been published.

The following section.

---Part 1: Single-use sharps containers;

---Part 2: Reusable sharps containers.

This document is a modified version of ISO 23907-2:2019 "Requirements and test methods for protection against sharp objects - Part 2: Reusable sharp objects".

container".

The technical differences between this document and ISO 23907-2:2019, and the reasons therefor, are as follows.

---ISO 7864 has been replaced with the normatively referenced GB 15811 (see 6.3.1.2) to adapt to my country's technical conditions and improve operability.

Acting.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Syringes (Needles) (SAC/TC95).

Introduction

GB/T 46388 "Requirements and Test Methods for Protection Against Sharp Object Injuries" is proposed to consist of two parts.

---Part 1: Single-use sharps containers. The purpose is to specify the requirements for single-use sharps containers and to provide a reference method.

---Part 2: Reusable Sharps Containers. The purpose is to specify the requirements for reusable sharps containers and to provide a reference method.

Sharps injury protection requirements and test methods Part 2: Reusable Sharps Containers

1 Scope

This document specifies the reusable sharps (with or without sharps protection) intended for the disposal of potentially hazardous sharps medical waste.

Specific requirements for containers (such as scalpels, cannulas, injection needles, and syringes) describe the corresponding test methods.

This document applies to fully-packaged containers supplied by the manufacturer and containers intended to be assembled by the user from supplied bulk components (hereinafter referred to as...).

(Referring to "sharp container").

This document does not apply to single-use sharps containers (see GB/T 46388.1-2025 for such containers).

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

GB 15811 Single-use sterile injection needles (GB 15811-2016, ISO 7864:1993, NEQ)
GB/T 46388.1-2025 Requirements and test methods for protection against sharps injuries - Part 1: Single-use sharps containers (ISO 23907-1:2019, MOD)

3 Terms and Definitions

The terms and definitions defined in GB/T 46388.1-2025, as well as the following terms and definitions, apply to this document.

Clean

No visible stains, debris, or organic matter.

Decontamination

Remove stains from sharps containers using physical, chemical, or thermal methods, and inactivate or kill pathogens to prevent the spread of infectious diseases.

Handling and using sharps containers provides safety.

Note: See 4.5 for the decontamination process.

Lifespan

The maximum number of use and/or processing cycles confirmed by the producer.

Representative sharp A representative number of unused syringe needles ranging from 1mL to 60mL, of which 70% have safety mechanisms activated.

All devices are equipped with safety devices, while 30% of syringe needles lack safety features.

processing

A proven method for making used sharps containers safe to handle and reuse.