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

GB/T 46388.1-2025

**Sharps injury protection - Requirements and test methods -
Part 1: Single-use sharps containers**

锐器伤害保护 要求和试验方法 第1部分：一次性使用锐器容器

(English Translation)

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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 1 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 23907-1:2019 "Requirements and test methods for protection against sharp objects - Part 1: Single-use sharp objects - Sharp objects - Protective equipment - Protection against injury - Sharp objects - Protective equipment...

Containers.

The technical differences between this document and ISO 23907-1:2019, and the reasons therefor, are as follows.

---ISO 7864 has been replaced with the normatively referenced GB 15811 (see 5.3.1.2) 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 46388-2025 "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 1: Single-use sharps containers

1 Scope

This document specifies the requirements for the disposal of potentially hazardous sharps medical waste (with or without sharps protection) for single-use sharps.

The specific requirements for containers of instruments (such as scalpels, cannulas,

injection needles, and syringes) are described, along with the corresponding test methods.

This document applies to pre-packaged single-use sharps containers supplied by the manufacturer and to bulk components intended for assembly by the user.

Single-use sharps containers (hereinafter referred to as "sharps containers").

This document does not apply to reusable sharps containers or outer containers used for shipping single-use sharps 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)

3 Terms and Definitions

The following terms and definitions apply to this document.

Opening Aperture

An opening in a sharps (3.15) container for disposing of discarded sharps (3.15).

closure feature

A cap, plug, lid, or sliding device for closing an opening (3.1).

Filling line

A mark, symbol, or structure on a sharps container indicating the filling volume (3.4).

Filling volume

The available volume indicated by the fill line (3.3) on the sharps container as clearly stated by the manufacturer.

handle

An attachment, protrusion, flange, or notch used to move a container of sharps.

Integrated connection to be permanently fixed or attached to a sharps container.