
**Sharps injury protection —
Requirements and test methods —**

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

*Protection contre les blessures par perforants — Exigences et
méthodes d'essai —*

Partie 1: Conteneurs à usage unique pour objets piquants ou coupants

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and catheters*.

This first edition cancels and replaces the first edition (ISO 23907:2012), which has been technically revised. The main changes compared to the previous edition are as follows:

- Resistance to penetration: increase of the force to a minimum of 16 N;
- Addition of yellow as the base dominant colour;
- Creation of [Annex A](#) “Additional explanation of the rationale underpinning this document” and deletion of the previous Annexes A and B;
- New requirements for the permanent and temporary closures;
- New requirements on resistance to damage or leakage after toppling;
- Clarification of the procedure for the resistance to penetration and the resistance to damage and leakage after dropping test methods;
- Addition of a new test method for resistance to spillage by toppling.

A list of all parts in the ISO 23907 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Sharps injury protection — Requirements and test methods —

Part 1: Single-use sharps containers

1 Scope

This document specifies requirements for single-use sharps containers intended to hold potentially hazardous sharps medical waste with or without sharps protection features, e.g. scalpel blades, trocars, hypodermic needles and syringes.

It is applicable to single-use sharps containers that are supplied complete by the manufacturer and to those that are supplied as components intended to be assembled by the user.

It is not applicable to reusable sharps containers or to the outer containers used in the transportation of filled single-use sharps containers.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

ISO 7864, *Sterile hypodermic needles for single use — Requirements and test methods*

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1

aperture

opening of the *sharps* (3.15) container through which *sharps* (3.15) are deposited for disposal

3.2

closure feature

flap, plug, lid or slide that is intended to close the *aperture* (3.1)

3.3

fill line

mark, indicator or feature on the container that represents the *fill volume* (3.4)

3.4

fill volume

usable volume determined by the manufacturer and indicated by the *fill line* (3.3) on the container

3.5

handle

appendage, protrusion, flange or recess intended for lifting the container

3.6

integrally attached

tethered or joined to the container by a permanent means

3.7

leak-resistance

ability of a container to prevent escape of fluid

Note 1 to entry: See conditions specified in [5.4](#).

3.8

manufacturer's allowable gross mass

maximum mass of the container and contents as recommended by the manufacturer for safe handling and operation

Note 1 to entry: Mass shall be measured in kilograms (kg).

3.9

needle disconnection feature

feature allowing single-handed *sharps* ([3.15](#)) disconnection

3.10

penetration

movement of a needle through the *test specimen* ([3.19](#)) until the point of the needle exits on the side opposite the point of entry

3.11

penetration force

amount of force applied to a hypodermic needle to achieve *penetration* ([3.10](#))

Note 1 to entry: The penetration force is expressed in newtons (N).

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Note 2 to entry: See conditions specified in [5.3](#).

3.12

permanent closure

closure feature ([3.2](#)), *integrally attached* ([3.6](#)) to the container, which once activated cannot be re-opened manually

3.13

pocket collectors

sharps ([3.15](#)) container that has a *fill volume* ([3.4](#)) equal to or less than 0,6 l

Note 1 to entry: The primary design considerations for pocket collectors are to prevent *penetration* ([3.10](#)) of the *sharp(s)* ([3.15](#)) through the container while providing a compact size that can be easily carried on the person of the user, such as in the user's pocket. In order to achieve portability and a low profile, these devices have been excluded from certain aspects of the requirements of this document.

3.14

secondary stabilizer

attachment or design feature intended to provide extra stability and prevent the device from toppling over