
Zaščita pred poškodbami z ostrimi predmeti - Zahteve in preskusne metode - 3.
del: Vsebniki za ostre predmete (ISO 23907:2012)

Sharps injury protection - Requirements and test methods - Part 3: Sharps containers
(ISO 23907:2012)

Schutz vor Stich- und Schnittverletzung - Anforderungen und Prüfverfahren - Behälter für
spitze und scharfe Abfälle (ISO 23907:2012)

Protection contre les blessures par perforants - Exigences et méthodes d'essai -
Conteneurs pour objets coupants, tranchants et perforants (ISO 23907:2012)

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 23907

September 2012

ICS 11.040.99

English Version

**Sharps injury protection - Requirements and test methods -
Sharps containers (ISO 23907:2012)**

Protection contre les blessures par perforants - Exigences
et méthodes d'essai - Conteneurs pour objets coupants,
tranchants et perforants (ISO 23907:2012)

Schutz vor Stich- und Schnittverletzung - Anforderungen
und Prüfverfahren - Behälter für spitze und scharfe Abfälle
(ISO 23907:2012)

This European Standard was approved by CEN on 31 August 2012.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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Contents

Page

Foreword.....	3
---------------	---

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[SIST EN ISO 23907:2012](https://standards.iteh.ai/catalog/standards/sist/d6fdc34d-6b9b-4830-8d57-3c40b878182b/sist-en-iso-23907-2012)

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Foreword

This document (EN ISO 23907:2012) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and intravascular catheters" in collaboration with Technical Committee CEN/TC 205 "Non-active medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

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INTERNATIONAL STANDARD

ISO
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First edition
2012-09-01

Sharps injury protection — Requirements and test methods — Sharps containers

*Protection contre les blessures par perforants — Exigences et méthodes
d'essai — Conteneurs pour objets coupants, tranchants et perforants*

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3c40b878182b/sist-en-iso-23907-2012](https://standards.iteh.ai/catalog/standards/sist/d6fdc34d-6b9b-4830-8d57-3c40b878182b/sist-en-iso-23907-2012)



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Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 23907 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

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ISO 23907:2012(E)**Introduction**

Single-use sharps containers are designed for the containment and disposal of sharps such as scalpel blades, trocars, hypodermic needles and syringes. They are supplied in a wide range of sizes and can be manufactured from a variety of materials. This International Standard does not specify the size range of the containers or the materials selected to manufacture the containers.

Sharps containers can be either single-use or reusable. This International Standard covers single-use sharps containers. The test methods included in this International Standard might be applicable when developing a reusable sharp container standard.

This International Standard includes informative annexes with rationales on several subjects, which have undergone profound debate in ISO/TC 84. These rationales have been elaborated to provide further explanation on the present requirements. In future editions of this International Standard, these rationales will also clarify the justification of the current requirements.

National regulations exist in some countries; their requirements might supersede or complement this International Standard.

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Sharps injury protection — Requirements and test methods — Sharps containers

1 Scope

This International Standard 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 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 the outer containers used in the transportation of filled single-use sharps containers.

2 Normative references

The following referenced documents are indispensable for the application 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*

3 Terms and definitions

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

3.1

aperture

opening of the sharps container in which sharps are inserted for disposal

3.2

closure feature

flap, plug, lid or slide that is intended to close the aperture

3.3

permanent closure

condition when the closure feature is locked/sealed in preparation for final disposal

3.4

total volume of the container

entire air space in a closed container

3.5

fill volume of the container

usable volume determined by the manufacturer and indicated by the fill line on the container

3.6

fill line indicator

mark or indicator on the container that represents the fill volume

3.7

handle

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