

# **SLOVENSKI STANDARD**

## **oSIST prEN ISO 23907-1:2017**

**01-december-2017**

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**Zaščita pred poškodbami z ostrimi predmeti - Zahteve in preskusne metode - 1.  
del: Vsebniki za ostre predmete za enkratno uporabo (ISO/DIS 23907-1:2017)**

Sharps injury protection - Requirements and test methods - Part 1: Single-use sharps containers (ISO/DIS 23907-1:2017)

Schutz vor Stich- und Schnittverletzung - Anforderungen und Prüfverfahren - Teil 1: Einmalbehälter für spitze und scharfe Abfälle (ISO/DIS 23907-1:2017)

Protection contre les blessures par perforants - Exigences et méthodes d'essai - Partie 1: Conteneurs pour objets coupants, tranchants et perforants (ISO/DIS 23907-1:2017)

**Ta slovenski standard je istoveten z: prEN ISO 23907-1**

**ICS:**

11.040.99	Druga medicinska oprema	Other medical equipment
13.100	Varnost pri delu. Industrijska higiena	Occupational safety. Industrial hygiene

**oSIST prEN ISO 23907-1:2017**

**de**



# DRAFT INTERNATIONAL STANDARD

## ISO/DIS 23907-1

ISO/TC 84

Secretariat: DS

Voting begins on:  
2017-10-04Voting terminates on:  
2017-12-27

### 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 pour objets coupants, tranchants et perforants*

ICS: 11.040.99

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**ISO/CEN PARALLEL PROCESSING**



Reference number  
ISO/DIS 23907-1:2017(E)

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**ISO/DIS 23907-1:2017(E)****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](http://www.iso.org/directives)).

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For an explanation on 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 the following URL: [www.iso.org/iso/foreword.html](http://www.iso.org/iso/foreword.html).

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

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

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## Introduction

Guidance on transition periods for implementing the requirements of this document is given in ISO/TR 19244.

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# 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 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 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 <http://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

#### 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

##### **fill line indicator**

mark or indicator on the container that represents the fill volume

#### 3.4

##### **fill volume of the container**

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

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**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 under the conditions specified in this document

**3.8****manufacturer's allowable gross mass**

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

**3.9****needle disconnection feature**

feature allowing single-handed sharp disconnection

**3.10****penetration**

movement of a needle through the test specimen 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](#)) under the conditions specified in this document

Note 1 to entry: The penetration force is expressed in Newtons.

**3.12****permanent closure**

closure feature which once activated prior to final disposal, cannot be re-opened manually

**3.13****pocket collectors**

sharps container that has a total capacity equal to or less than 0,75 l, intended to contain a limited number of sharps

Note 1 to entry: The primary design considerations for pocket collectors is to prevent *penetration* ([3.10](#)) of the sharp(s) 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 when placed on a horizontal or vertical surface

**3.15****sharps**

objects capable of cutting or penetrating skin

EXAMPLE Needles of various types, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, exposed ends of dental wires.