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Sharps injury protection - Requirements and test methods - Part 1: Single-use sharps containers (ISO 23907-1:2019)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 06/19

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 23907-1**

February 2019

ICS 11.040.99

Supersedes EN ISO 23907:2012

English Version

**Sharps injury protection - Requirements and test methods  
- Part 1: Single-use sharps containers (ISO 23907-1:2019)**

Protection contre les blessures par perforants -  
Exigences et méthodes d'essai - Partie 1: Conteneurs à  
usage unique pour objets piquants ou coupants (ISO  
23907-1:2019)

Schutz vor Stich- und Schnittverletzung -  
Anforderungen und Prüfverfahren - Teil 1:  
Einmalbehälter für spitze und scharfe Abfälle (ISO  
23907-1:2019)

This European Standard was approved by CEN on 21 December 2018.

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.

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**EN ISO 23907-1:2019 (E)**

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## **European foreword**

This document (EN ISO 23907-1:2019) has been prepared by Technical Committee ISO/TC 84 "Devices for administration of medicinal products and 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of an identical text or by endorsement, at the latest by August 2019, and conflicting national standards shall be withdrawn at the latest by February 2020.

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

This document supersedes EN ISO 23907:2012.

According to the CEN-CENELEC Internal Regulations, the national standards organizations 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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

## **Endorsement notice**

The text of ISO 23907-1:2019 has been approved by CEN as EN ISO 23907-1:2019 without any modification.

# INTERNATIONAL STANDARD

# ISO 23907-1

First edition  
2019-01

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## 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*



Reference number  
ISO 23907-1:2019(E)

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**ISO 23907-1:2019(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)).

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](http://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](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*.

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](http://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*

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**