SLOVENSKI STANDARD
SIST EN ISO 23907-1:2019

01-april-2019

Nadomešča:
SIST EN ISO 23907:2012

Zaščita pred poškodbami z ostrimi predmeti - Zahteve in preskusne metode - 1. del: Vsebniki za ostre predmete za enkratno uporabo (ISO 23907-1:2019)

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

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

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ICS:

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

SIST EN ISO 23907-1:2019 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23907-1

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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.

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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Contents

Page

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

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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Contents

Page

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).

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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