ICS 11.040.25 SLOVENSKÁ TECHNICKÁ NORMA November 2025

STN	**Ochrana pred bodným a rezným poranením Ochranné prvky pred bodným a rezným poranením pre injekčné ihly na jednorazové použitie, katétrové zavádzače a ihly používané na testovanie krvi, monitorovanie, odber vzoriek a podávanie liečivých látok Požiadavky a skúšobné metódy (ISO 23908: 2024)**	**STN EN ISO 23908** 85 6120

Sharps injury protection - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration - Requirements and test methods (ISO 23908:2024)

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. 10/25

Obsahuje: EN ISO 23908:2025, ISO 23908:2024

Oznámením tejto normy sa ruší
STN EN ISO 23908 (85 6120) z júla 2013

141352

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23908

August 2025

ICS 11.040.25 Supersedes EN ISO 23908:2013

English Version

Sharps injury protection - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration - Requirements and test methods (ISO 23908:2024)

Protection contre les blessures par perforants - Mécanismes de protection des aiguilles à usage unique, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements, le contrôle et l'échantillonnage sanguins et l'administration de substances médicales - Exigences et méthodes d'essai (ISO 23908:2024)

Schutz vor Stich- und Schnittverletzung - Anforderungen und Prüfverfahren - Schutzmechanismen für einmalig zu verwendende Kanülen, Einführhilfen für Katheter und Kanülen für Bluttests, Überwachung, Probenahme und Verabreichung medizinischer Substanzen (ISO 23908:2024)

This European Standard was approved by CEN on 12 December 2024.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

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

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

Ref. No. EN ISO 23908:2025 E

Contents

Page

European foreword

This document (EN ISO 23908:2025) 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 February 2026, and conflicting national standards shall be withdrawn at the latest by February 2026.

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 23908:2013.

This document has been prepared under a standardization request addressed to CEN by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 23908:2024 has been approved by CEN as EN ISO 23908:2025 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail. In this context, the definition of 'device' in EN ISO 23908 is limited to products in the scope of the standard and differs from the definition of 'medical device' in Regulation (EU) 2017/745.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 This Annex ZA is based on normative references according to the table of references in Table ZA.2, replacing the references in the core text.

NOTE 4 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.

Table ZA.1 — Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
4a) 4b) 4c)	5.1.3, 5.1.4, 5.1.5, 5.1.6, 5.2, 5.3.	Covered. Intent of these clauses is to provide adequate level of user safety through safe design. Activation/safe mode is required to be communicated to the user in a clear and unmistakable manner at least by a persistent visual indication. Reference is included to precautions, warnings and training needs. There are no foreseen contraindications.
5	5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.1.6, 5.1.7	Covered with respect to reducing risks related to ergonomic features and the environment in which the device is intended to be used, giving consideration of intended users (including homecare patients, caregivers, lay persons and disabled persons), by requiring the application of an appropriate usability engineering program.
8	5, 6, 7	Covered. Intent of these clauses is to provide adequate level of user safety except for the following devices (excluded from the scope) because their SIPMs have been found to adversely affect the usability and can increase the risk for patients versus the benefit of the intended use of the device: Devices for medication loading and transfer, where blunt tip design would be required. Invasive products whose intended use is to access small spaces, particularly ear, nose and throat and ophthalmic procedures.
11.1 a) and b)	5.1.1, 5.1.2, 5.1.3, 5.1.4, 5.1.5, 5.1.6, 5.2, 5.3	Covered provided that the SIPM is integrated as part of the device before use, including any

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / subclause(s) of this EN	Remarks / Notes
		required pre-use assembly.
14.1	7.3 b)	Covered with respect of providing assembly instructions in the instructions for use to obtain a safe combination, where applicable.
14.7	5.1.4, 6.3, 7.3 e)	Covered in part. Subclause 5.1.4 requires the mechanism to provide protection against unintentional sharp injury until safe disposal and 7.3e) requires provision of instructions for safe disposal of the actuated protection mechanism. The requirements for testing formative or summative user interface evaluations include protection until safe disposal of the sharp but specific test procedures are not provided.
22.1	5.1.2, 5.2, 5.3, 7.1	Covered.
22.2	5, 6, 7	Covered provided that the SIPM is integrated as part of the device before use, including any required pre-use assembly.
22.3	5.1.4, 5.1.6	In part. Warning if the device has failed to perform as intended is not covered.
23.1 first paragraph	7	Covered with respect to identifying in the instructions for use the correct devices and SIPM and providing assembly instructions to obtain a safe combination, where applicable.

Table ZA.2 — Normative references from Clause 2 of this document and their corresponding European publications

Reference in Clause 2	International Standard Edition	Title	Corresponding European Standard Edition
ISO 14971:2019	ISO 14971:2019	Medical devices — Application of risk management to medical devices	EN ISO 14971:2019 +A11:2021
ISO 16269-6:2014	ISO 16269-6:2014	Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals	/
IEC 62366-1: 2015+A1:2020	IEC 62366-1: 2015+A1:2020	Medical devices — Part 1: Application of usability engineering to medical devices	EN 62366-1:2015
ISO 11608-1:2022	ISO 11608-1:2022	Needle-based injection systems for medical use – Requirements and test methods – Part 1: Needle-based injection systems	EN ISO 11608-1:2022
ISO 20417:2021	ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer	EN ISO 20417:2021

The documents listed in the Column 1 of Table ZA.2, in whole or in part, are normatively referenced in this document, i.e. are indispensable for its application. The achievement of the presumption of conformity is subject to the application of the edition of Standards as listed in Column 4 or, if no European Standard Edition exists, the International Standard Edition given in Column 2 of Table ZA.2.

WARNING 1 Presumption of conformity stays valid only as long as a reference to this European Standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

International Standard

ISO 23908

Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods

Protection contre les blessures par perforants — Mécanismes de protection des aiguilles à usage unique, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements, le contrôle et l'échantillonnage sanguins et l'administration de substances médicales — Exigences et méthodes d'essai

Second edition
2024-12

Reference number
ISO 23908:2024(en)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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 document 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).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at www.iso.org/patents. ISO shall not be held responsible for identifying any or all such patent rights.

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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 205, *Non-active medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 23908:2011), which has been technically revised.

The main changes are as follows:

— the Scope has been expanded to cover single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration;

— reference has been made to medical devices standards ISO 14971, IEC 62366-1, ISO 11608-1, ISO 20417;

— a free fall test has been added, with as a pass/fail the non-access to the sharps, in order to cover a frequent misuse situation and avoid a potential increase of the risk of sharp injury;

— updates on the test methods Gauge R&R requirements for destructive testing (threshold becoming no greater than 30 % of the specification interval for destructive test, instead of 20 % for any other given measurement);

— a new requirement for A-SIPM has been introduced to include both obvious and non-obvious misuse situations in the risk assessment and to mitigate these situations as far as possible through product design;

— a new requirement has been added to apply a minimum force of 5 N to challenge access to the sharp;

— normative Annex A has been revised to include the methods for testing the access to the sharp in safe mode and after free fall;

— device and SIPM recovery has been added as a potential option to include in the device life cycle.

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.

Introduction

This document addresses sharps injury protection mechanism designed to protect users and others who can incidentally be exposed to such devices post-use. These sharps injury protection mechanisms are intended to prevent, or reduce the potential risk for, disease transmission which can result from accidental, post-use sharps injuries.

This document addresses devices primarily intended for human use, of a wide range of product types, including but not limited to hollow-bore needles for injection or infusion of therapeutics into the body, or sampling of fluids from the body, and hollow-bore or solid-core needles used for blood sampling (e.g. lancing devices).

Given the broad variation in product design, categories of device, and sharps protection technologies, and in order to avoid unnecessarily restricting innovation, this document has been developed to provide general design, testing and labelling requirements, rather than specific physical and prescriptive design requirements. It therefore differs from documents which list specific maximum forces, detailed test fixture designs, test systems to be used or detailed test measures, as such prescriptive details cannot cover the variety of designs and devices. Including such details can impede continuing innovation in new products, mechanisms and/or protection mechanisms that lead to future improvements in healthcare.

This document presumes that the product developer uses a risk-based approach (consistent with ISO 14971:2019) to determine the device design that best meets the needs of a target user population and expected use settings. Through this risk-based approach, the sharps injury protection mechanism would have performance requirements appropriate to the foreseeable risks associated with the intended use of the device, expected user interfaces and the settings in which these sharps injury protection mechanisms are expected to be used.

This document provides guidelines to enable the manufacturer to verify that the design of the sharps injury protection mechanism complies with the design intent spelled out in the design specification.

As part of this validation, the manufacturer is expected to demonstrate that the performance of the sharps injury protection mechanism is appropriate to the intended users and settings through the use of appropriate formative or summative user interface evaluations. These studies allow the manufacturer to demonstrate that, when used in accordance with the instructions for use, in settings representative of real-life intended use and by intended or foreseeable users, the mechanism functions as intended.

The standards ISO 23907-1 (covering single-use sharps containers, revised in 2019), and ISO 23907-2 (covering reusable sharps containers, created in 2019), have significantly improved the prevention of health risks and the safety for all the persons that manipulate post-use sharps medical devices.

However, taking into account the need to intensify the security of sharps medical devices post-use as well as the growing need to reduce their environmental impact by encouraging the possibility of allowing their recycling, this revision constitutes an additional tool for the user's health protection and the preservation of the environment.

International Standard **ISO 23908:2024(en)**

Sharps injury protection — Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration — Requirements and test methods

1 Scope

This document provides requirements and test methods to evaluate the performance and usability of sharps injury protection mechanisms (SIPMs) of devices including a single use sharp, for administration and/or extraction of blood or body fluids and/or medicinal substances.

The sharps injury protection mechanisms covered by this document can be provided integral to the device or for assembly with the device prior to use.

The aim of the tests is to confirm minimization of risks of accidental sharps injury from contaminated sharps, after the period of intended use, including the path to safe disposal or recovery, where this is a legal requirement or the manufacturers' decision.

This document does not cover

— devices for medication loading and transfer, utilizing a blunt tip design, or

— invasive products whose intended use is to access small spaces, particularly ear, nose and throat, to perform ophthalmic procedures

because their SIPMs have been found to adversely affect the usability and can increase the risk for patients versus the benefit of the intended use of the device.

This document does not cover solid-core needles used for surgery (e.g. suture needles).

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 11608-1:2022, *Needle-based injection systems for medical use — Requirements and test methods — Part 1: Needle-based injection systems*

ISO 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 16269-6:2014, *Statistical interpretation of data — Part 6: Determination of statistical tolerance intervals*

IEC 62366-1:2015+Amd1:2020, *Medical devices — Part 1: Application of usability engineering to medical devices*

ISO 20417:2021, *Medical devices — Information to be supplied by the manufacturer*