SLOVENSKI STANDARD
oSIST prEN ISO 23908:2023

01-december-2023

Zaščita pred poškodbami z ostrimi predmeti - Zahteve in preskusne metode - Mehanizmi za zaščito pri uporabi podkožnih igel za enkratno uporabo, nastavkov za uvedbo katetra in igel za odvzem krvi, spremljanje, vzorčenje in apliciranje zdravil (ISO/DIS 23908:2023)

Sharps injury protection - Requirements and test methods - Sharps protection mechanisms for single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration (ISO/DIS 23908:2023)

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/DIS 23908:2023)

Protection contre les blessures par perforants - Exigences et méthodes d’essai - Mécanismes de protection des aiguilles à usage unique, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements sanguins, le contrôle, l’échantillonnage et l’administration de substances médicales (ISO/DIS 23908:2023)

Ta slovenski standard je istoveten z: **prEN ISO 23908**

ICS:

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles an catheters

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DRAFT INTERNATIONAL STANDARD

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

ICS: 11.040.25

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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.

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).

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).

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 84, *Devices for administration of medicinal products and catheters*.

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

The main changes are as follows:

- Scope has been enlarged to single-use needles, introducers for catheters and needles used for blood testing, monitoring, sampling and medical substance administration.
- Reliance on current medical devices standards: ISO 14971, IEC 62366-1, ISO 11608-1, ISO 20417.
- Addition of a falling test, 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 procedure to challenge the minimum overriding force of the SIPM in safe mode in order to cover the numerous design possibilities (threshold is no greater than 20 % of the specification interval for any given measurement, 30% for destructive test).
- For A-SIPM, misuse situations (obvious or non-obvious) shall be included in the risk assessment and be mitigated as far as possible by product design.

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.

European foreword

This document (pr EN ISO 23908:2023) 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 ……., and conflicting national standards shall be withdrawn at the latest by …….

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.

This document will supersede EN ISO 23908:2013.

This document has been prepared under a standardization request M/575 of 14.4.2021 given to CEN by the European Commission and the European Free Trade Association, and supports general safety and performance requirements of EU Regulation(s).

In particular, this European standard has been revised by describing technical solutions for safety-engineered mechanisms to be applied in design and manufacture of devices to ensure compliance with points 11.1 and 22.2 of Chapter II of Annex I to Regulation (EU) 2017/745. The term “device” within this document covers, products regulated as medical devices according Regulation (EU) 2017/745 and also product regulated as pharmaceutical or medicinal products.

For the relationship with EU Regulation(s) see informative Annex ZA, which is an integral part of this document.

When an IEC or ISO standard is referred to in the ISO standard text, this should be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard as listed in Table ZA.2. However, for any use of this standard within the meaning of Annex ZA, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 23908:2022 has been approved by CEN as EN ISO 23908:2022 without any modification.

Introduction

This document addresses sharps injury protection mechanism designed to protect users of medical devices. These sharps injury protection mechanisms are intended to prevent, or reduce the potential risk for, disease transmission which could result from accidental, post-use sharps injuries.

This document is aimed at addressing devices primarily intended for human use, of a wide range of product types, including, among others, 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). It addresses sharps injury protection mechanisms which are either active or passive in their activation after the device's intended use. It does not cover solid-core needles used for surgery (e.g. suture needles).

Given the broad variation in product design and sharps protection technology, the variety of different types of devices, and in order to avoid unnecessarily restricting innovation, this document has been developed to provides for general design, testing and labelling requirements, rather than specific physical and prescriptive design requirements. It therefore differs from standard 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, and may 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 would use 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 mechanism 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 verification, 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 simulated or clinical use studies. These simulated or clinical use 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.

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

1 Scope

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

The sharps injury protection mechanisms it covers can be provided integral to the device or combined with the device prior to use to achieve the sharps injury protection.

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.

It does not give requirements for the storage and handling of the device, sharps, or sharps protection before the sharp is used to penetrate the tissue.

The following devices are excluded from the scope because their SIPM 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, utilizing a blunt tip design;

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

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, *Medical devices — Part 1: Application of usability engineering to medical devices*

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

3 Terms and definitions

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

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
activation
complete deployment of the sharp's protection mechanism

3.2
active sharp injury protection mechanism
A-SIPM
sharps protection mechanism which requires an action to be carried out by the user (such as the deployment of a shield for the needle) separate from those actions required to perform the primary intended function of the *device* (3.6)

3.3
accidental sharps injury
unintentional penetration of *sharps* (3.10) into a human, other than the patient, at any time including during the *path to safe disposal* (3.8) or recovery, after having been used to penetrate the patient's human tissue

Note 1 to entry: All *sharps* (3.10) that have been used or discarded before use (for example expired *sharps* (3.10)), are considered as potentially contaminated sharps with blood borne pathogens which can be transmitted to another person through the sharp's injury.

Note 2 to entry: Injury with a sharp before use presents potential hazards other than transmission of blood borne pathogens (i.e. infection due to contamination and/or loss of sterility before use, or puncture or laceration), to the potential patient and others, and should be considered in the risk assessment.

3.4
contaminated sharps
sharp (3.10) that has penetrated human tissue, usually after administration and/or extraction of body/blood fluids and/or medicinal substances

Note 1 to entry: Such *sharps* (3.10) should be considered as having the potential to carry blood borne pathogens.

3.5
integrated (built-in) sharps injury protection mechanism
sharps injury protection mechanism (active or passive) that is provided to the user pre-assembled with the *device* (3.6) and is not designed to be separated

3.6
device
product for administration and/or extraction of body/blood fluids and/or medicinal substances

Note 1 to entry: This definition is given to understand device, as used in this document.

Note 2 to entry: For the propose of this document, the term device covers, products regulated as medical devices and product regulated as pharmaceutical or medicinal products.

3.7
passive (self-activating) sharp injury protection mechanism
P-SIPM
sharps protection mechanism that does not require a specific additional action by the user to activate, separate from any action needed to perform the primary intended function of the *device* (3.6)