



**BSI Standards Publication**

**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**

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This is a preview of BS EN ISO 23908:2025. [Click here to purchase the full version from the ANSI store.](#)

## National foreword

This British Standard is the UK implementation of EN ISO 23908:2025. It is identical to ISO 23908:2024. It supersedes BS EN ISO 23908:2013, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/84, Catheters and syringes.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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This publication has been prepared under a mandate given to the European Standards Organizations by the European Commission and the European Free Trade Association. It is intended to support requirements of the EU legislation detailed in the European Foreword. A European Annex, usually Annex ZA or ZZ, describes how this publication relates to that EU legislation.

For the Great Britain market (England, Scotland and Wales), if UK Government has designated this publication for conformity with UKCA marking (or similar) legislation, it may contain an additional National Annex. Where such a National Annex exists, it shows the correlation between this publication and the relevant UK legislation. If there is no National Annex of this kind, the relevant Annex ZA or ZZ in the body of the European text will indicate the relationship to UK regulation applicable in Great Britain. References to EU legislation may need to be read in accordance with the UK designation and the applicable UK law. Further information on designated standards can be found at [www.bsigroup.com/standardsandregulation](http://www.bsigroup.com/standardsandregulation).

For the Northern Ireland market, UK law will continue to implement relevant EU law subject to periodic confirmation. Therefore Annex ZA/ZZ in the European text, and references to EU legislation, are still valid for this market.

UK Government is responsible for legislation. For information on legislation and policies relating to that legislation, consult the relevant pages of [www.gov.uk](http://www.gov.uk).

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**Compliance with a British Standard cannot confer immunity from legal obligations.**

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 30 November 2025.

**Amendments/corrigenda issued since publication**

Date	Text affected
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## EUROPÄISCHE NORM

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.



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COMITÉ EUROPÉEN DE NORMALISATION  
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**CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels**

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## 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.

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## **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.

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**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)	<a href="#">5.1.3</a> , <a href="#">5.1.4</a> , <a href="#">5.1.5</a> , <a href="#">5.1.6</a> , <a href="#">5.2</a> , <a href="#">5.3</a> .	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	<a href="#">5.1.2</a> , <a href="#">5.1.3</a> , <a href="#">5.1.4</a> , <a href="#">5.1.5</a> , <a href="#">5.1.6</a> , <a href="#">5.1.7</a>	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	<a href="#">5</a> , <a href="#">6</a> , <a href="#">7</a>	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)	<a href="#">5.1.1</a> , <a href="#">5.1.2</a> , <a href="#">5.1.3</a> , <a href="#">5.1.4</a> , <a href="#">5.1.5</a> , <a href="#">5.1.6</a> , <a href="#">5.2</a> , <a href="#">5.3</a>	Covered provided that the SIPM is integrated as part of the device before use, including any

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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	<a href="#">7.3</a> b)	Covered with respect of providing assembly instructions in the instructions for use to obtain a safe combination, where applicable.
14.7	<a href="#">5.1.4</a> , <a href="#">6.3</a> , <a href="#">7.3</a> e)	Covered in part. <a href="#">Subclause 5.1.4</a> requires the mechanism to provide protection against unintentional sharp injury until safe disposal and <a href="#">7.3e)</a> 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	<a href="#">5.1.2</a> , <a href="#">5.2</a> , <a href="#">5.3</a> , <a href="#">7.1</a>	Covered.
22.2	<a href="#">5</a> , <a href="#">6</a> , <a href="#">7</a>	Covered provided that the SIPM is integrated as part of the device before use, including any required pre-use assembly.
22.3	<a href="#">5.1.4</a> , <a href="#">5.1.6</a>	In part. Warning if the device has failed to perform as intended is not covered.
23.1 first paragraph	<a href="#">7</a>	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.

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

Reference in <a href="#">Clause 2</a>	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.

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