Kaitse teravate esemetega tekitatud vigastuste eest. Nõuded ja katsemeetodid. Kaitsemeetmed teravike eest ühekordsete hüpotermiliste nõelte, vereproovide võtmiseks kasutatavate kateetrite otsikute ja nõelte korral

Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (ISO 23908:2011)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 23908:2011 sisaldab Euroopa standardi EN ISO 23908:2011 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 23908:2011 consists of the English text of the European standard EN ISO 23908:2011.
Standard on kinnitatud Eesti Standardikeskuse 30.06.2011 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.06.2011 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.06.2011.	Date of Availability of the European standard text 01.06.2011.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.25, 11.040.99

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23908

June 2011

ICS 11.040.99; 11.040.25

English Version

Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (ISO 23908:2011)

Protection contre les blessures par perforants - Exigences et méthodes d'essai - Dispositifs de protection des aiguilles hypodermiques, des introducteurs pour cathéters et des aiguilles utilisées pour les prélèvements sanguins, non réutilisables (ISO 23908:2011)

Schutz vor Stich- und Schnittverletzung - Anforderungen und Prüfverfahren - Schutzeinrichtungen für einmalig zu verwendende Nadeln zur subkutanen Injektion, Kathetereinführungen und Nadeln zur Blutentnahme (ISO 23908:2011)

This European Standard was approved by CEN on 31 May 2011.

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 23908:2011: E

Foreword

This document (EN ISO 23908:2011) 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 December 2011, and conflicting national standards shall be withdrawn at the latest by December 2011.

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 has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directives.

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

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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of ISO 23908:2011 has been approved by CEN as a EN ISO 23908:2011 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on Medical Devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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 Essential Requirements of that Directive and associated EFTA regulations.

NOTE This citation under the Directive 93/42/EEC is appropriate provided that the sharps protection is a feature integrated/associated to the medical device.

Table ZA.1 — Correspondence between this International Standard and Directive 93/42/EEC on Medical devices

Clause(s)/subclause(s) of this International Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clauses 4, 5 and 6	1	Design verification addresses user interface, labelling, general design requirements, environmental and testing
Clauses 4 and 6	2	
Clause 4 and 5	3	
Clause 4, 5.3, 5.4	4	
Clause 4, 5.5	6 & 6.a	
Clauses 4.1.1.1, 4.1.1.2, 4.1.1.3, 4.3, 5.3, 5.4, 5.5	8.1	
Clause 4.1.1.4	9.1	
Clause 4.1.1.1, 4.1.1.2, 4.1.1.3, 4.3, 5.3, 5.4, 5.5	9.2	
Clause 4.2, 5.2	12.7	
Clause 6	13	The part of ER 13.3.a) relating to the authorized representative and the part of ER 13.6.h) relating to single-use are not addressed in the standard

WARNING — Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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Introduction

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

This International Standard 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 systems which are either active or passive in their activation after the medical 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 International Standard has been developed as “horizontal” in nature, which means it provides for general design, testing and labelling requirements, rather than specific physical and prescriptive design requirements. It therefore differs from more “vertical” standards, 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, features and/or protection mechanisms that lead to future improvements in healthcare.

This International Standard presumes that the product developer would use a risk-based approach (consistent with ISO 14971) 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 system 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 safety features are expected to be used.

This International Standard provides guidelines to enable the manufacturer to verify that the design of the sharps injury protection systems 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 system 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 device functions as intended.

Existing products and those currently under development may not fulfil some of the requirements given by this International Standard. However, manufacturers would be well advised to follow its provisions when improving existing products or developing new products to obtain an even higher level of quality.

Sharps injury protection — Requirements and test methods — Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling

1 Scope

This International Standard gives requirements and test methods for evaluating the performance parameters of sharps injury protection features, whether active or passive in design, for medical devices containing (sharp) hypodermic needles for single use, introducers for catheters and lancets, and other needles used in blood sampling. The sharps injury protection devices it covers may be provided integral to the device or combined with the device prior to use to achieve the sharps injury protection.

It does not give requirements for the storage and handling of the sharps protection before its intended use, or for the medical device itself.

2 Normative references

The following referenced documents are indispensable for the application 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 2859 (all parts), *Sampling procedures for inspection by attributes*

ISO 3951 (all parts), *Sampling procedures for inspection by variables*

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

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

3 Terms and definitions

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

3.1
activation
deployment of the sharps protection mechanism

3.2
active safety feature
sharps protection feature that requires an additional step by the user to activate, separate from any action needed to perform the primary intended function of the device

3.3
accidental sharps injury
unintentional penetration into human tissue by the sharp after the intended use