SLOVENSKI STANDARD
SIST EN ISO 23908:2013

01-maj-2013

Nadomešča:
SIST EN ISO 23908:2011

Zaščita pred poškodbami z ostrimi predmeti - Zahteve in preskusne metode - Zaščitni ukrepi pri uporabi podkožnih igel za enkratno uporabo, nastavkov za uvedbo katetra in igel za odvzem krvi (ISO 23908:2011)

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)

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)

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)

Ta slovenski standard je istoveten z: **EN ISO 23908:2013**

ICS:

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

SIST EN ISO 23908:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 23908

February 2013

ICS 11.040.25; 11.040.99

Supersedes EN ISO 23908:2011

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)

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This European Standard was approved by CEN on 8 January 2013.

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

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

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Ref. No. EN ISO 23908:2013: E

Contents

Foreword

The text of ISO 23908:2011 has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and intravascular catheters” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 23908:2013 by 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 2013, and conflicting national standards shall be withdrawn at the latest by August 2013.

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 supersedes EN ISO 23908:2011.

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 Directive.

For relationship with EU Directive, 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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 23908:2011 has been approved by CEN as EN ISO 23908:2013 without any modification.

Annex ZA
(informative)

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

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 European Standard and Directive 93/42/EEC on Medical Devices

Clause(s)/subclause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4.1.1.1, 4.1.1.2, 4.1.1.3, 4.3, 5.3, 5.4, 5.5	8.1	
4.1.1.4	9.1	
4.1.1.1, 4.1.1.2, 4.1.1.3, 4.3, 5.3, 5.4, 5.5	9.2	
4.2, 5.2	12.7	
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.

INTERNATIONAL STANDARD

ISO 23908

First edition
2011-06-11

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

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 23908 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

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.