SLOVENSKI STANDARD
SIST EN ISO 10555-1:2013

01-november-2013

Nadomešča:

SIST EN ISO 10555-1:2009

Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 1. del: Splošne zahteve (ISO 10555-1:2013, popravljena verzija 2013-07-01)

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2013, Corrected version 2013-07-01)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 1: Allgemeine Anforderungen (ISO 10555-1:2013, korrigierte Fassung 2013-07-01)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 1: Exigences générales (ISO 10555-1:2013, Version corrigé 2013-07-01)

Ta slovenski standard je istoveten z: EN ISO 10555-1:2013

ICS:

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

SIST EN ISO 10555-1:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1

July 2013

ICS 11.040.25

Supersedes EN ISO 10555-1:2009

English Version

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2013, Corrected version 2013-07-01)

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This European Standard was approved by CEN on 29 May 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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Foreword

This document (EN ISO 10555-1:2013, Corrected version 2013-07-01) 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 January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.

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 10555-1:2009.

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(s).

For relationship with EU Directive(s), 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 10555-1:2013, Corrected version 2013-07-01 has been approved by CEN as EN ISO 10555-1:2013 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC amended by Directive 2007/47/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 a means of conforming to Essential Requirements of Directive 93/42/EEC amended by Directive 2007/47/EEC.

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 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 relevant Essential Requirements of that Directive.

NOTE When an Essential 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 Directive 93/42/EEC amended by Directive 2007/47/EEC

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 10555-1
7.3	4.5* 4.9 4.10*
7.5	4.4*
8.1	4.1* 6.2 c) and d)*
8.3	4.1* 6.2 c) and d)*
8.4	4.1**** 6.2 d)*
9.1	4.8 4.9 4.10 6.3 b), c) and i)
9.2	4.2 4.4 4.6 4.7 4.8 4.9 4.10 4.11 4.12 5
12.7.1**	4.4 4.6 4.7 4.9 4.10

	4.11 4.12
12.7.4	4.9 4.10
12.8.1	4.9 4.10
13.1	6.1 6.2 a), b), f), g), h), i), j), k) 6.4
13.2	6.1
13.3 a)	6.2 a)
13.3 b)	6.2 b)
13.3 c)	6.2 c)
13.3 d)	6.2 e)
13.3 e)	6.2 f)
13.3 f)	6.2 g)
13.3 i)	6.2 h)
13.3 j)	6.2 i) and j) 6.3 c) and i)
13.3 k)	6.3 b) and f)
13.3 m)	6.2 d)
13.4	6.2 i) 6.3 a)
13.6 a)	6.3 a) ***
13.6 b)	6.3 b)
13.6 c)	6.3 c) and f)
13.6 e)	6.3 f)
13.6 f)	6.3 g)
13.6 g)	6.3 d)
13.6 k)	6.3 b) and f)
13.6 l)	6.3 b) and g)
13.6 n)	6.3 e)
13.6 q)	6.3 h)

(*) Not fully covered as the requirements are depended on the specific product.

(**) For the user, only 4.7 is applicable.

(***) Method of sterilisation not required in the instruction for use as it is required on the device or primary packing.

(****) Only concerning sterilisation aspects.

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

INTERNATIONAL STANDARD

ISO 10555-1

Second edition
2013-06-15

Corrected version
2013-07-01

Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 1: Exigences générales

Reference number
ISO 10555-1:2013(E)

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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 10555-1 was prepared by Technical Committee ISO/TC 84, *Devices for administration of medicinal products and intravascular catheters*.

This second edition cancels and replaces the first edition (ISO 10555-1:1995), which has been technically revised. It also incorporates the amendments ISO 10555-1:1995/Amd 1:1999 and ISO 10555-1:1995/Amd 2:2004.

ISO 10555 consists of the following parts, under the general title *Intravascular catheters — Sterile and single-use catheters*:

— *Part 1: General requirements*

— *Part 3: Central venous catheters*

— *Part 4: Balloon dilatation catheters*

— *Part 5: Over-needle peripheral catheters*

The following part is under preparation:

— *Part 6: Subcutaneous implanted ports*

The following part has been withdrawn and the content has been included in ISO 10555-1:

— *Part 2: Angiographic catheters*

Attention is drawn to ISO 11070, which specifies requirements for accessory devices for use with intravascular catheters.

This corrected version of ISO 10555-1:2013 incorporates an editorial correction in H.2.

