



# SLOVENSKI STANDARD SIST EN ISO 10555-5:2013

01-november-2013

Nadomešča:

SIST EN ISO 10555-5:2000

SIST EN ISO 10555-5:2000/A1:2000

SIST EN ISO 10555-5:2000/AC:2002

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**Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 5. del: Periferni katetri z notranjo iglo (ISO 10555-5:2013)**

Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:2013)

STANDARD PREVIEW

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Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 5: Periphere Katheter mit innen liegender Kanüle (ISO 10555-5:2013)

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Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 5: Cathéters périphériques à aiguille interne (ISO 10555-5:2013)

**Ta slovenski standard je istoveten z: EN ISO 10555-5:2013**

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**ICS:**

11.040.25	Injekcijske brizge, igle in katetri	Syringes, needles and catheters
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**SIST EN ISO 10555-5:2013**

**en**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

**EN ISO 10555-5**

July 2013

ICS 11.040.25

Supersedes EN ISO 10555-5:1997

English Version

## Intravascular catheters - Sterile and single-use catheters - Part 5: Over-needle peripheral catheters (ISO 10555-5:2013)

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Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 5: Periphere Katheter mit innen liegender Kanüle (ISO 10555-5:2013)

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.

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

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## Foreword

This document (EN ISO 10555-5:2013) 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 10555-5:1997.

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.

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### Endorsement notice

The text of ISO 10555-5:2013 has been approved by CEN as EN ISO 10555-5:2013 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 10555-5
7.3	4.1
7.5	4.1
8.1	4.1
8.3	4.1
8.4	4.1
9.1	4.1 4.3.3.3
9.2	4.1 4.2 4.3.3.2 4.3.3.3 4.3.3.4 4.3.4
12.7.1	4.1 4.3.3.2
12.7.4	4.1
12.8.1	4.1
12.9	4.2
13.1	4.1
13.2	4.1

13.3 a)	4.1
13.3 b)	4.1
13.3 c)	4.1
13.3 d)	4.1
13.3 e)	4.1
13.3 f)	4.1
13.3 i)	4.1
13.3 j)	4.1 4.4 a) and c)
13.3 k)	4.1 4.4 b)
13.3 m)	4.1
13.4	4.1
13.6 a)	4.1
13.6 b)	4.1
13.6 c)	4.1
13.6 e)	4.1
13.6 f)	4.1
13.6 g)	4.1
13.6 k)	4.1
13.6 l)	4.1
13.6 n)	4.1
13.6 q)	4.1

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

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INTERNATIONAL  
STANDARD

ISO  
10555-5

Second edition  
2013-06-15

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**Intravascular catheters — Sterile and  
single-use catheters —**

Part 5:  
**Over-needle peripheral catheters**

*Cathéters intravasculaires — Cathéters stériles et non réutilisables —*

*Partie 5: Cathéters périphériques à aiguille interne*

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