SLOVENSKI STANDARD
SIST EN ISO 10555-3:2013

01-november-2013

Nadomešča:
SIST EN ISO 10555-3:2000
SIST EN ISO 10555-3:2000/AC:2002

Žilni katetri - Sterilni žilni katetri za enkratno uporabo - 3. del: Osrednji venski katetri (ISO 10555-3:2013)

Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters (ISO 10555-3:2013)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 3: Zentrale venöse Katheter (ISO 10555-3:2013)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 3: Cathéters veineux centraux (ISO 10555-3:2013)

Ta slovenski standard je istoveten z: **EN ISO 10555-3:2013**

ICS:

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

SIST EN ISO 10555-3:2013 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-3

July 2013

ICS 11.040.25

Supersedes EN ISO 10555-3:1997

English Version

Intravascular catheters - Sterile and single-use catheters - Part 3: Central venous catheters (ISO 10555-3:2013)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 3: Cathéters centraux veineux (ISO 10555-3:2013)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 3: Zentrale venöse Katheter (ISO 10555-3:2013)

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.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 10555-3:2013) 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 10555-3:1997.

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.

Endorsement notice

The text of ISO 10555-3:2013 has been approved by CEN as EN ISO 10555-3:2013 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 10555-3
7.3	4.1
7.5	4.1
8.1	4.1
8.3	4.1
8.4	4.1
9.1	4.1
9.2	4.1 4.2 4.3 4.4
12.7.1	4.1 4.4
12.7.4	4.1
12.8.1	4.1
12.9	4.2* 4.3*
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
13.3 k)	4.1 4.5 d)
13.3 m)	4.1
13.4	4.1
13.6 a)	4.1
13.6 b)	4.1 4.5 a), b) and c)
13.6 c)	4.1
13.6 e)	4.1
13.6 f)	4.1
13.6 g)	4.1
13.6 h	4.5 c)**
13.6 k)	4.1
13.6 l)	4.1
13.6 n)	4.1
13.6 q)	4.1
(*) Not applicable for the patient. **(**)** The information is on cleaning even though it is not a reusable devices.	

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

INTERNATIONAL STANDARD

ISO 10555-3

Second edition
2013-06-15

Intravascular catheters — Sterile and single-use catheters —

Part 3: Central venous catheters

Cathéters intravasculaires — Cathéters stériles et non réutilisables —

Partie 3: Cathéters centraux veineux

Reference number
ISO 10555-3:2013(E)