Steriilsed ühekordselt kasutatavad intravaskulaarsed (soonesisesed) kateetrid. Osa 3: Tsentraalveenikateetrid

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

EESTI STANDARDIKESKUS
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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 10555-3:2013 sisaldab Euroopa standardi EN ISO 10555-3:2013 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10555-3:2013 consists of the English text of the European standard EN ISO 10555-3:2013.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 10.07.2013.	Date of Availability of the European standard is 10.07.2013.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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EUROPÄISCHE NORM

EN ISO 10555-3

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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.

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

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Ref. No. EN ISO 10555-3:2013: E

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.

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Intravascular catheters — Sterile and single-use catheters —

Part 3: Central venous catheters

1 Scope

This part of ISO 10555 specifies requirements for central venous catheters supplied in the sterile condition, and intended for single use.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 10555-1:2013, *Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 10555-1 and the following apply.

3.1
central venous catheter
intravascular catheter, single- or multilumen, designed for introduction into, or withdrawal of liquids from, the central venous system and/or for pressure or other measurements

Note 1 to entry: The catheter can have a fixation system which is part of the device.

4 Requirements

4.1 General

Catheters shall comply with ISO 10555-1, except for the peak tensile force (see ISO 10555-1:2013, 4.6), for which the requirements of 4.4 of this part of ISO 10555 shall apply.

4.2 Distance markings

If the catheter is provided with distance markings, the marking system shall indicate distance from the distal end. From the first mark, the distance between marks shall not exceed 5 cm.

It is recommended that the distance marks be 1 cm apart on that portion of the catheter likely to be of importance to the user in positioning the catheter and monitoring catheter migration.

4.3 Lumen markings

For multilumen catheters, identification of each lumen shall be apparent to the user.