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Steriilsed ühekordselt kasutatavad intravaskulaarsed (soonesisesed) kateetrid. Osa 5: Üle nõela paigaldatavad perifeersed kateetrid

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

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See Eesti standard EVS-EN ISO 10555-5:2013 sisaldab Euroopa standardi EN ISO 10555-5:2013 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10555-5:2013 consists of the English text of the European standard EN ISO 10555-5:2013.
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.
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ICS 11.040.25

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-5

July 2013

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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)

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

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

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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of an identical text or by endorsement, at the latest by January 2014, and conflicting national standards shall be withdrawn at the latest by January 2014.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.

Endorsement notice

The text of ISO 10555-5:2013 has been approved by CEN as EN ISO 10555-5:2013 without any modification.

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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

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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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Intravascular catheters — Sterile and single-use catheters —

Part 5: Over-needle peripheral catheters

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1 Scope

This part of ISO 10555 specifies requirements for over-needle peripheral intravascular catheters, intended for accessing the peripheral vascular system, 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 594-1, *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 1: General requirements*[1)]

ISO 9626, *Stainless steel needle tubing for the manufacture of medical devices*

ISO 10555-1, *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
over-needle peripheral intravascular catheter
catheter designed for the introduction or withdrawal of liquids or devices into or from the peripheral vascular system

3.2
needle
assembly comprising at least a needle tube attached to, and communicating with, a needle hub

See Figure 1.

3.3
needle tube
rigid tube with one end sharpened to facilitate entry into body tissue

3.4
needle hub
fitting attached to the needle tube, providing communication with its bore

3.5
vent fitting
fixed or removable fitting permitting venting of air while restricting or preferably preventing the escape of blood

1) Upon its publication, ISO 80369-7 will replace ISO 594-1 and ISO 594-2.

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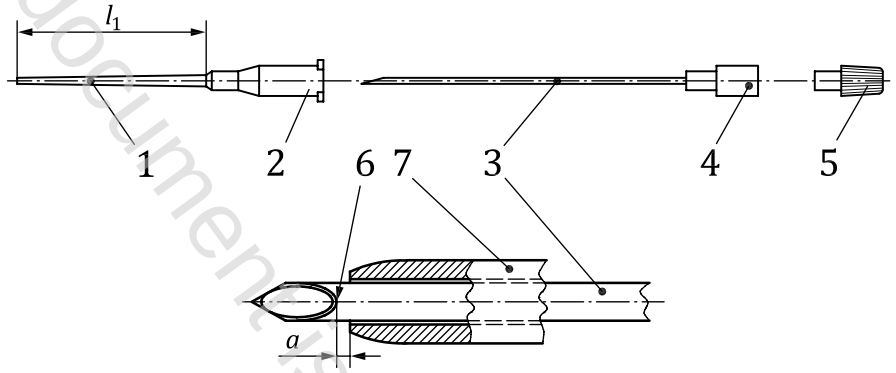
3.6
catheter unit
assembly comprising the catheter tube, catheter hub and any integral fittings

See Figure 1.

3.7
flashback
blood flow into the needle hub



Key

a	$0 < a < 1$ mm (see 4.3.2)
l_1	effective length
1	catheter tube
2	catheter hub
3	needle tube
4	needle hub
5	vent fitting
6	heel of bevel
7	catheter unit

NOTE Other design features may include wings, injection ports integral with the catheter hub, other means of connecting to the fluid path, protection against accidental needle stick injury, etc. The catheter tube may have a single lumen or multiple lumens.

Figure 1 — Typical over-needle peripheral intravascular catheter

4 Requirements

4.1 General

Unless otherwise specified in this part of ISO 10555, over-needle peripheral catheters shall comply with ISO 10555-1.

4.2 Multilumen catheters

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

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