Steriilsed ühekordselt kasutatavad intravaskulaarsed (soonesisesed) kateetrid. Osa 1: Üldnõuded

Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements (ISO 10555-1:2013)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 10555-1:2013 sisaldab Euroopa standardi EN ISO 10555-1:2013 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10555-1:2013 consists of the English text of the European standard EN ISO 10555-1:2013.
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.

ICS 11.040.25

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-1

July 2013

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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)

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

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

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 10555-1:2013: E

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.

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Intravascular catheters — Sterile and single-use catheters —

Part 1: General requirements

1 Scope

This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application.

lt is not applicable to intravascular catheter accessories, e.g. those covered by ISO 11070.

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 594-2, *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment — Part 2: Lock fittings*[1)]

ISO 7886-1, *Sterile hypodermic syringes for single use — Part 1: Syringes for manual use*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
intravascular catheter
tubular device, single or multilumen, designed to be partially or totally inserted or implanted into the cardiovascular system for diagnostic and/or therapeutic purposes

3.2
distal end
end of the catheter inserted furthest into the patient

3.3
distal end configuration
shape of the catheter which is designed to facilitate its manual manipulation through the cardiovascular system and the placement and anchoring of the distal tip in the chosen location

3.4
proximal end
access end
end of the catheter to which connection can be made

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

3.5
hub
connector(s) at the proximal end of the catheter which may either be integral with the catheter or be capable of being securely fitted to the proximal end of the catheter

3.6
effective length
l
length of the catheter, or pre- and post-hydration lengths of hydratable catheters that can be inserted into the body

SEE: Figure 1.

3.7
outside diameter
largest diameter of the catheter or pre- and post-hydration largest diameters of hydratable catheters that can be inserted into the vessel

3.8
junction
the joining of one tube or more tubes, where the assembly of the tubes provide mechanical support in tension/compression during clinical use

3.9
hydratable intravascular catheter
intravascular catheter consisting of a material that manifests clinically significant hydration when subjected to an aqueous medium

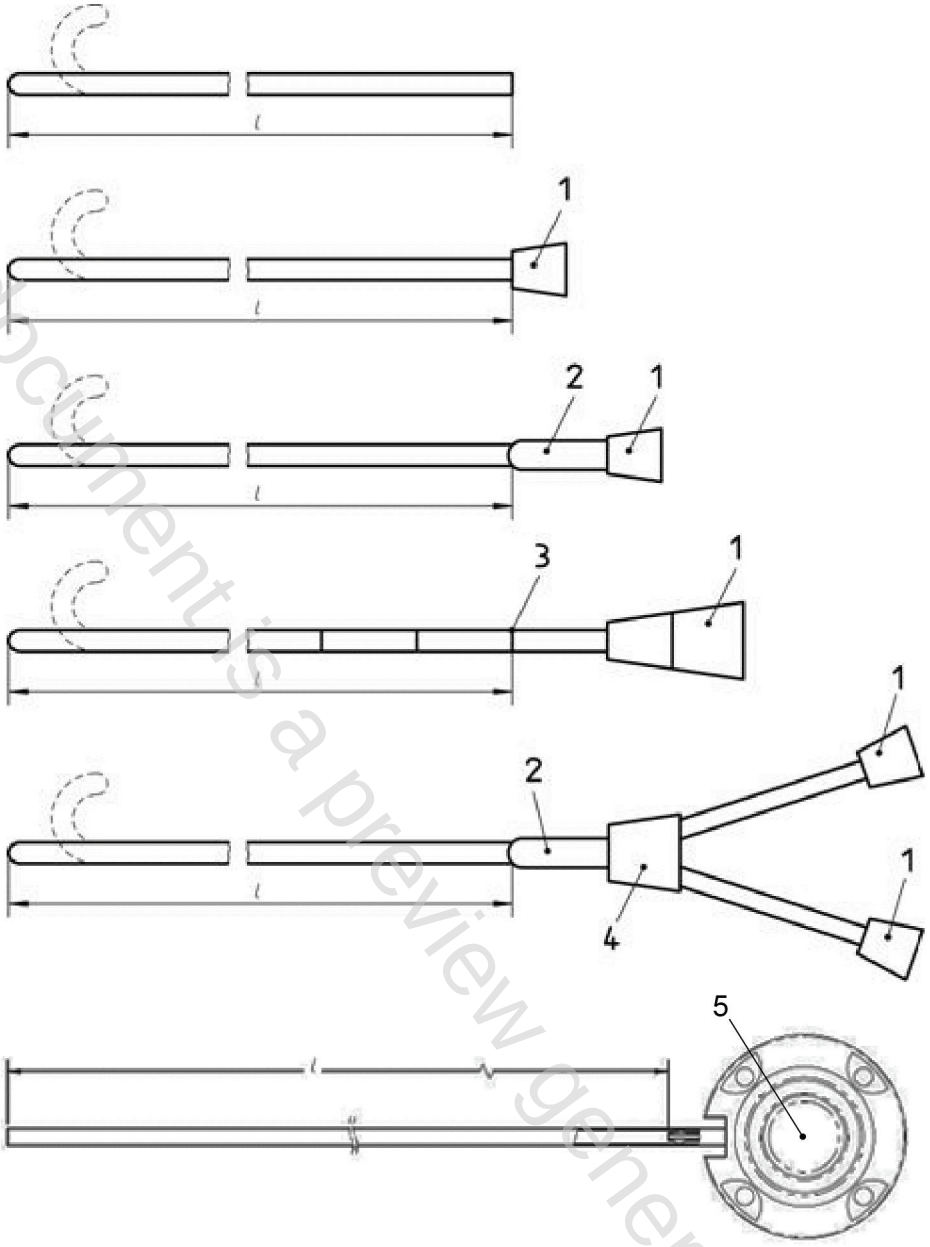
3.10
post-hydration
state of a hydratable intravascular catheter after immersion in aqueous medium at (37 ± 2) °C for a clinically appropriate period of time

3.11
clinically significant hydration
hydrated state in which either the post-hydration effective length is greater than the pre-hydration effective length by more than 1 % of the effective length, or the post-hydration outside diameter is greater than the pre-hydration outside diameter by 10 % or more

3.12
power injection
rapid injection of fluid at high pressure

3.13
primary packaging
packaging which has direct contact with the device and/or maintains the sterility of the product

3.14
secondary packaging
packaging designed to contain one or more primary packages



Key

l effective length
1 catheter hub
2 catheter strain reinforcement
3 length mark
4 junction
5 pre-connected port

Figure 1 — Examples of effective length of catheters

3.15
angiographic catheter
intravascular catheter used for the injection of contrast media and/or fluids and which may be used for pressure measurements and to obtain blood samples or insertion of coaxial inner catheter, occlusion coils or other devices