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INTRAVASKULAARSED KATEETRID. STERIILSED ÜHEKORDSELT KASUTATAVAD INTRAVASKULAARSED KATEETRID. OSA 6: NAHAALUNE IMPLANTEERITUD VEENIPORT

Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports (ISO 10555-6:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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See Eesti standard EVS-EN ISO 10555-6:2017 sisaldab Euroopa standardi EN ISO 10555-6:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 10555-6:2017 consists of the English text of the European standard EN ISO 10555-6:2017.
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 23.08.2017.	Date of Availability of the European standard is 23.08.2017.
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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10555-6

August 2017

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English Version

Intravascular catheters - Sterile and single-use catheters - Part 6: Subcutaneous implanted ports (ISO 10555-6:2015)

Cathéters intravasculaires - Cathéters stériles et non réutilisables - Partie 6: Chambres à cathéter implantables (ISO 10555-6:2015)

Intravaskuläre Katheter - Sterile Katheter zur einmaligen Verwendung - Teil 6: Subkutan implantierte Ports (ISO 10555-6:2015)

This European Standard was approved by CEN on 30 July 2017.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Ref. No. EN ISO 10555-6:2017 E

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European foreword

The text of ISO 10555-6:2015 has been prepared by Technical Committee ISO/TC 84 “Devices for administration of medicinal products and catheters” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10555-6:2017 by 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 February 2018, and conflicting national standards shall be withdrawn at the latest by February 2018.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard ‘within the meaning of Annex ZA’, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlation between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 10555-1:2013	EN ISO 10555-1:2013	ISO 10555-1:2013
ISO 10555-3:2013	EN ISO 10555-3:2013	ISO 10555-3:2013

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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, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 10555-6:2015 has been approved by CEN as EN ISO 10555-6:2017 without any modification.

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Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of Directive 93/42/EEC [OJ L 169] aimed to be covered

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This European standard has been prepared under a Commission's standardisation request M/295 concerning the development of European Standards related to medical devices to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 corresponding essential requirements of that Directive, and associated EFTA regulations.

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced 'as far as possible', 'to a minimum', 'to the lowest possible level', 'minimized' or 'removed', according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with essential requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

NOTE 3 This Annex ZA is based on normative references according to the table of references in the European foreword, replacing the references in the core text.

NOTE 4 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 Annex I of Directive 93/42/EEC [OJ L 169]

Essential Requirements (ER) of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
7.5	4.2	ER 7.5 is covered only in respect of biocompatibility. Covers lubricants limited size drops on surfaces in design and manufacturing.
9.1	4.5.3, 4.5.6.1, 6.4 g)	ER 9.1 is covered by Standard Clause 4.5.3 in respect of leakage only. ER 9.1 is covered by Standard Clause 4.5.6.1 only in respect of peak tensile force between the port and the catheter. ER 9.1 is covered by Standard Clause 6.4g only in respect of specifications of the devices required to connect the port to the power injector. The connection must be standardized. The maximum for the connected injector. The intended purpose should be stated on the label

Essential Requirements (ER) of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		or in the instruction for use, if not obvious. A pressure limit and maximum flowrate is required in the instruction for use, if the catheter is indicated for power injection. Covers restrictions on use indicated on labelling.
9.2	4.5.3, 4.5.4, 4.6, 4.7, 5	ER 9.2 first dash is covered by Standard Clause 4.5.3 in respect of leakage only. ER 9.2 first dash is covered by Standard Clause 4.5.4 in respect of the flushing volume only. ER 9.2 first dash is covered by Standard Clause 4.6 in respect of the flow rate only. ER 9.2 first dash is covered by Standard Clause 4.7 in respect of the burst pressure. ER 9.2 second dash is covered by Standard Clause 5 in respect of MRI compatibility only. The risk of injury, in connection with physical features including the volume/pressure ratio and dimensional features in the design process.
12.7.1	4.5.3, 4.6.2, 4.7.2	ER 12.7.1 is covered by Standard Clause 4.5.3 in respect of leakage only. ER 12.7.1 is covered by Standard Clause 4.6.2 in respect of flow rate only. ER 12.7.1 is covered by Standard Clause 4.7.2 in respect of burst pressure only. The catheter and port must be designed to protect the patient.
12.9	4.3	ER 12.9 is covered in respect of distance marking on the catheter only. Indicators for length adjustment.
13.3 a)	6.3	Standard Clause 6.3 first dash covers ER 13.3 a) but only in respect of the name of the manufacturer and only provided the labels are located as required by the Directive.
13.3 b)	6.1, 6.3	Standard Clause 6.1 covers ER 13.3 b) only in respect of the marking on the actual product. Standard Clause 6.3 second and third dash covers ER 13.3 b) but only in respect of the designation and item number and Batch/Lot/serial number.
13.3 d)	6.3	ER 13.3 d) is covered by Standard Clause 6.3 third dash but only when the any batch code is preceded by the word 'LOT'. Label and traceability label
13.4	6.2, 6.4	ER 13.4 is covered by Standard Clause 6.2 but only in respect of identification of power injection.

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Essential Requirements (ER) of Directive 93/42/EEC	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
		ER 13.4 is covered by Standard Clause 6.2 but only in respect of the information given in Standard Clause 6.4 a-g.
13.6 a)	6.4	
13.6 b)	6.4	Only covers devices for power injection.
13.6 c)	6.4 g)	
13.6 d)	6.4 c), d)	
13.6 e)	6.4 a)	
13.6 f)	6.4 e)	
13.6 i)	6.4 g)	
13.6 l)	6.4 e)	Precautions to be taken as regards exposure in reasonably foreseeable environmental conditions to magnetic fields.
13.6 n)	6.4	Does not specify 'unusual risk'.
13.6 q)	6.4	

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

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