SÜDAME-VERESOONKONNA IMPLANTAADID. SOONESISESED VAHENDID. OSA 1: SOONESISESED PROTEESID

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 25539-1:2017 sisaldab Euroopa standardi EN ISO 25539-1:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 25539-1:2017 consists of the English text of the European standard EN ISO 25539-1:2017.
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 15.03.2017.	Date of Availability of the European standard is 15.03.2017.
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 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 25539-1

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Supersedes EN ISO 25539-1:2009

English Version

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2017)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 1: Prothèses endovasculaires (ISO 25539-1:2017)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 1: Endovaskuläre Prothesen (ISO 25539-1:2017)

This European Standard was approved by CEN on 23 December 2016.

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

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

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European foreword

This document (EN ISO 25539-1:2017) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 "Non-active surgical implants" 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 September 2017 and conflicting national standards shall be withdrawn at the latest by March 2020.

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 25539-1:2009.

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

Endorsement notice

The text of ISO 25539-1:2017 has been approved by CEN as EN ISO 25539-1:2017 without any modification.

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 — Correlations between undated normative references and dated EN and ISO standards

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	**ISO**
ISO 10993 (all parts)	EN ISO 10993-1:2009 EN ISO 10993-2:2006 EN ISO 10993-3:2014 EN ISO 10993-4:2009 EN ISO 10993-5:2009 EN ISO 10993-6:2009 EN ISO 10993-7:2008 and EN ISO 10993-7:2008/AC:2009 EN ISO 10993-9:2009 EN ISO 10993-10:2013 EN ISO 10993-11:2009 EN ISO 10993-12:2012 EN ISO 10993-13:2010 EN ISO 10993-14:2009 EN ISO 10993-15:2009 EN ISO 10993-16:2010 EN ISO 10993-17:2009 EN ISO 10993-18:2009 - -	ISO 10993-1:2009 ISO 10993-2:2006 ISO 10993-3:2014 ISO 10993-4:2002 and Amd 1:2006 ISO 10993-5:2009 ISO 10993-6:2007 ISO 10993-7:2008 and ISO 10993-7:1/Cor 1:2009 ISO 10993-9:2009 ISO 10993-10:2010 ISO 10993-11:2006 ISO 10993-12:2012 ISO 10993-13:2010 ISO 10993-14:2001 ISO 10993-15:2000 ISO 10993-16:2010 ISO 10993-17:2002 ISO 10993-18:2005 ISO/TS 10993-19:2006 ISO/TS 10993-20:2006
ISO 11135	EN ISO 11135:2014	ISO 11135:2014
ISO 11137 (all parts)	EN ISO 11137-1:2015 EN ISO 11137-2:2015 EN ISO 11137-3:2006	ISO 11137-1:2006 and Amd 1:2013 ISO 11137-2:2013 ISO 11137-3:2006
ISO 11607-1	EN ISO 11607-1:2009 and EN ISO 11607-1:2009/A1:2014	ISO 11607-1:2006 and Amd 1:2014
ISO 14155	EN ISO 14155:2011	ISO 14155:2011 and Cor. 1:2011
ISO 14160	EN ISO 14160:2011	ISO 14160:2011
ISO 14630:2012	EN ISO 14630:2012	ISO 14630:2012
ISO 14937	EN ISO 14937:2009	ISO 14937:2009
ISO 14971	EN ISO 14971:2012	ISO 14971:2007
ISO 17665 (all parts)	EN ISO 17665-1:2006 CEN ISO/TS 17665-2:2009	ISO 17665-1:2006 ISO/TS 17665-2:2009

Annex ZA
(informative)

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

This European Standard has been prepared under a Commission's standardisation request M/023 concerning the development of European standards related to medical devices to provide a 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 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 of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN	Remarks/Notes
7.2	11.2	Partially covered by the sub-clause: There is a requirement for devices to be designed to protect patients from *sterilization* residuals when the device is used. Other contaminants and residues are not covered. Manufacturing and packing to minimize these risks are not covered.
8.1	11.1, 12.1.5	Partially covered by the sub-clauses: Requirements for ensuring sterility are included for devices that are supplied

		sterile (11.1) which would eliminate or reduce as far as possible the risk of infection to the patient. Maintenance of sterility in transit is covered in 12.1.5. Risk of infection to the user and third party are not covered. Minimizing contamination during use is not covered.
8.3	11.1, 12.1, 10 with 6.4(c)	Sterility assurance (11.1), manufacturing (10), packaging design and maintenance of sterility (12.1) are covered. 6.4(c) includes the requirement for the design attributes to take the need for sterility into account.
8.4	11.1, 10 with 6.4(c)	Manufacturing (10), sterilization validation and routine control (11.1) are covered, with the requirement for the design attributes to take the need for sterility into account (6.4(c)).
9.1	8.5.1.5, 12.3.2(i)	Endovascular systems may be designed to be used with accessory devices (e.g., guide wires, introducer sheaths). Accessory devices are evaluated for compatibility with the endovascular system in simulated use testing (8.5.1.5). Requirements regarding instructions for use include preparation and implantation techniques including the use of ancillary devices (12.3.2(i)).
9.2, first indent	4.3, 6.2, 6.3, 8.5.1.2, 8.5.2.7, 8.5.1.5	Partially covered by the sub-clauses: Device design is covered through the requirement to specify dimensions (4.3), design attribute requirements (6.2 and 6.3) and the requirements

		for dimensional verification (8.5.1.2, 8.5.2.7). The risk of injury to the patient is also covered through simulated use testing (8.5.1.5). Manufacturing to minimize risks associated with physical features is not covered.
9.2, second indent	6.3 (g), 8.5.2.9	Only risks associated with magnetic fields is covered through design attribute (6.3(g)) and MRI safety (8.5.2.9) requirements. The other environmental conditions are not applicable.
13.1	12.2, 12.3	The labelling (12.2) and instructions for use (12.3) sub-clauses cover this directive.
13.3(a)	12.2.1(a)	Partially covered by the sub-clause: This directive is covered with the exception of the requirement regarding the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community.

13.3(b)	12.2.1(b), (c), (d), (e), (f)	Identification of the device and the contents of the packaging is covered:
		12.2.1
		b) product name;
		c) the material of construction and type of construction;
		d) the configuration (see 4.3). A symbol may be substituted for a written description of the prosthesis;
		e) the nominal length(s);
		f) the nominal diameter(s);

13.3(c)	12.2.1(g)	The inclusion of the word 'STERILE' on the product label is covered by the requirement to include the words "STERILE—DO NOT RESTERILIZE—SINGLE USE

		ONLY", or equivalent phrase or symbols, in prominent form per the sub-clause.
13.3(d)	12.2.1(k)	This directive is covered by the requirement to include the manufacturer's batch or lot number per the sub-clause, but only if the batch code is preceded by the word 'LOT.'
13.3(e)	12.2.1(j)	This directive is covered by the requirement to include the date of sterilization and/or expiration date per the sub-clause.
13.3(f)	12.2.1(g)	Partially covered by the sub-clause: This directive is covered by the requirement to include the words 'SINGLE USE ONLY' per the sub-clause. Consistency of marking across the community is not covered.
13.3(i)	12.2.1(m)	Partially covered by the sub-clause: This directive is covered by the requirement to include the manufacturers recommendations for storage (when applicable) per the sub-clause. Handling is not covered.
13.3(k)	12.2.1(l)	Partially covered by the sub-clause: The only warning that is included indicates not to use if the package is opened or damaged.
13.3(m)	12.2.1(h)	This directive is covered by the requirement to include the method of sterilization per the sub-clause.
13.4	12.3.2(d)	This directive is covered. The intended purpose is obvious, but the intended use is required to be specified in the instructions for use per the sub-clause.
13.6(a) [13.3(a),(b), (c), (f), (i), (j), (k)]	12.3.2(a), (b), (c), (i), (j), (l), (e)	Partially covered by the sub-clauses: This directive is covered as follows: • 13.3 (a) is covered by

		12.3.2 (a) with the exception of the name and address of the authorised representative where the manufacturer does not have a registered place of business in the Community, nor the method of sterilization. • 13.3(b) is covered by 12.3.2(b), (c) • 13.3(c) is covered by 12.3.2(j) • 13.3(f) is covered by 12.3.2(j) • 13.3(i) is covered by 12.3.2(l) with the exception of handling • 13.3(j) is covered by 12.3.2(i) • 13.3(k) is covered by 12.3.2(e)
13.6(b)	12.3.2(f), (g)	This directive is covered with respect to the inclusion of any undesirable side effects by the requirement to include the potential adverse events (12.3.2(f) and performance information by the requirement to include data from clinical studies (if applicable) (12.3.2(g)).
13.6(c)	12.3.2(i)	Use of endovascular systems involves the use of additional medical devices (e.g., syringes, wire guides). This directive is covered by the requirement to include recommended methods for the preparation of the endovascular system and implantation techniques per the sub-clause.
13.6(d)	12.3.2(i)	The requirement to include recommended methods for the preparation of the endovascular system and implantation techniques per the sub-clause covers the

		directive regarding proper installation and preparation for operation. The directive regarding maintenance and calibration is not applicable as endovascular prostheses do not require maintenance and calibration.
13.6(g)	12.2.1(l), 12.3.2(j)	Partially covered by the sub-clauses: This directive is covered under the labelling requirement regarding not to use the device if the package is opened or damaged (12.2.1(l)), but not under the instructions for use. The directive regarding resterilization is covered by the requirement to state not to resterilize in the instructions for use (12.3.2(j)).
13.6(i)	12.3.2(i)	The directive regarding details of further handling is covered by the requirement to include recommended methods for the preparation of the endovascular system and implantation techniques per the sub-clause.
13.6(l)	12.3.2(n)	Only precautions associated with magnetic fields are covered through the requirement to provide MRI safety information per the sub-cluase. The other environmental conditions are not applicable.
13.6(q)	12.3.2 (o)	This directive is covered through the requirement to include the revision date for the instructions for use per the sub-clause.

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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