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STN	**Srdcovo-cievne implantáty Vnútrocievne pomôcky Časť 1: Vnútrocievne protézy (ISO 25539-1: 2017)**	**STN EN ISO 25539-1 85 2925**

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 08/17

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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.

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Ref. No. EN ISO 25539-1:2017 E

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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of an identical text or by endorsement, at the latest by September 2017 and conflicting national standards shall be withdrawn at the latest by September 2017.

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.

STN EN ISO 25539-1: 2017

INTERNATIONAL STANDARD

ISO 25539-1

Second edition
2017-02

Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

Implants cardiovasculaires — Dispositifs endovasculaires —

Partie 1: Prothèses endovasculaires

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www. iso. org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www. iso. org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso. org/iso/foreword. html.

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO 25539-1:2003), which has been technically revised.

It also incorporates the Amendment ISO 25539-1:2003/Amd1:2005.

A list of all the parts of ISO 25539 can be found on the ISO website.

Introduction

This document was prepared to provide minimum requirements for endovascular prostheses. The normative requirements are provided in the main body. The rationale for the requirements for bench tests and analyses to assess device performance, guidance on the identification of appropriate testing to evaluate a specific device design and guidance for developing test methods are provided in informative annexes. Further clarification of terminology and a cross reference between the main body and these annexes are provided in additional informative annexes.

This document has been updated to reflect current knowledge regarding the testing and clinical use of endovascular prostheses, reflected in modifications to the requirements in the main body and in the guidance for developing test methods in Annex D. In addition, revisions have been made to improve consistency in nomenclature and reporting and to enhance the utility of this document.

This document introduces methodology to identify appropriate testing and analyses for specific endovascular prosthesis, designated as the device evaluation strategy (DES). The requirement regarding the DES is in the main body, with informative guidance for the preparation of a DES table included in Annex A. Annex A also provides guidance for developing a DES for device design modifications and changes in intended use.

The other significant modifications in the requirements include the addition of non-radial durability testing, with guidance on the selection of appropriate testing, and specific requirements for testing to evaluate patency-related characteristics. Guidance for the development of appropriate tests to meet these requirements is included in Annex D.

The guidance on the development of methods to address the requirement for evaluating fatigue and durability through computational analyses has been modified significantly to include recommendations regarding verification of the solution and validation of the computational model, as well as reporting. The guidance on the model development for simulated use has also been significantly revised to improve the clinical relevance of this testing.

New requirements also include the evaluation of leakage at a seal zone and dislodgement force of endovascular prosthesis from a balloon. Guidance for the development of appropriate tests to meet these requirements is included in Annex D.

The requirement for evaluating the strength of the connection(s) between the graft material and a discrete fixation system(s) has been clarified with respect to the applicability of this requirement, that is, this requirement is only applicable for prostheses with a fixation system that is discrete from any stent(s) intended to provide structural support within the prosthesis [e.g. suprarenal stent that is not continuous with the stent(s) in the prosthesis body].

The specific requirements to evaluate pushability, flexibility, torquability, trackability and deployment accuracy of an endovascular system have been removed and incorporated within the simulated use evaluation requirement to better reflect how these attributes are evaluated. Similarly, the requirement to evaluate tubing tensile strength has been removed and incorporated within the evaluation of tensile bond strength.

The requirement to evaluate stent-free surface area has been removed as this attribute is not relevant for endovascular prostheses, which includes covered stents.

In addition to modifications to specific design evaluation requirements, guidance has been provided regarding the assessment of the acceptability of test results. When the requirement is to quantitatively appraise or analyse a parameter, test results generally may be compared to a quantitative value (i.e. acceptance criteria). For characterization tests, it is appropriate to provide an explanation of the relevance of the results. Additionally, some testing may include comparison to test data or existing data from a previously evaluated device.

For design evaluation, requirements regarding sampling, conditioning of test samples and reporting have been incorporated in the main body. Guidance on these elements of testing and documentation were previously included in Annex D.

The revisions to the titles of the annexes to this document are as follows.

Annex	ISO 25539-1:2003+A1:2005	ISO 25539-1:2017
A	Attributes of endovascular devices — Technical and clinical considerations	Relationship between testing requirements and device attributes and potential failure modes
B	Bench and analytical tests	Description of device and clinical effects of failure
C	Definitions of reportable clinical events	Bench and analytical tests
D	Test methods	Test methods
E	Sample equations as a supplement to the radial fatigue and durability test	There is no Annex E as this information was incorporated in Annex D

It is recognised by this ISO committee that many endovascular systems have been shown to be safe and effective in clinical use. This update is not intended to require additional evaluation of these devices to remain in compliance with this document as the testing would not provide useful information regarding the expected clinical performance of the device. Manufacturers may rely on historical data gathered under the guidance of the previous version of this document. Similarly, for device modifications or changes in intended clinical use, this update is not intended to require additional evaluation of any aspects of the device that are not expected to change clinical performance.

INTERNATIONAL STANDARD **ISO 25539-1:2017(E)**

Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

1 Scope

This document specifies requirements for the evaluation of endovascular systems (prostheses and delivery systems) and requirements with respect to nomenclature, design attributes and information supplied by the manufacturer based upon current medical knowledge. Guidance for the development of *in vitro* test methods is included in an informative annex to this document. This document can be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

This document is applicable to endovascular systems used to treat aneurysms, stenoses or other vascular anomalies or pathologies (e.g. dissections, transections) or to create shunts between vessels [e.g. creation of transjugular intrahepatic portosystemic shunting (TIPS)]. Some of the requirements are specific to endovascular treatment of arterial aneurysms or stenoses. Although uses of endovascular systems other than treatment of arterial aneurysms or stenoses (e.g. dissections, transections, shunts) are within the scope of this document, the specific requirements and testing are not described. Similarly, specific prosthesis configurations (e.g. fenestrated, branched) are within the scope, but specific requirements and testing are not described for these devices.

This document is not applicable to vascular occluders, with the exception of contra-lateral iliac artery occluders when used as an integral part of aorto-uni-iliac endovascular prosthesis. Although contra-lateral iliac artery occluders when used as an integral part of aorto-uni-iliac endovascular prosthesis are within the scope of this document, specific requirements and testing are not described for these devices.

Balloons used to achieve adequate apposition of the prosthesis with the vessel wall or overlapping components are within the scope of this document, even if they are not integral to the endovascular system. This document provides requirements beyond the requirements of ISO 10555-4, specific to the use of balloons with endovascular prostheses.

This document is not applicable to procedures and devices used prior to the introduction of the endovascular system, such as balloon angioplasty devices.

The valve component of valved conduits constructed with an endovascular prosthesis component and the combination of the valved component and the endovascular prosthesis component are excluded from the scope of this document. This document can be helpful in identifying the appropriate evaluation of the endovascular prosthesis component of a valved conduit, but specific requirements and testing are not described for these devices.

NOTE 1 Cardiac valved conduits are within the scope of ISO 5840-1.

Pharmacological aspects of drug eluting or drug coated endovascular prostheses are not addressed in this document.

NOTE 2 Vascular device-drug combination products are within the scope of ISO 12417.

This document does not address the requirements for, and the evaluation of, viable tissues and non-viable biologic materials used in the construction of endovascular prostheses.

The requirements for, and the evaluation of, degradation and other time-dependant aspects of absorbable materials used in the construction of endovascular prostheses are not addressed in this document.

NOTE 3 Absorbable materials are within the scope of ISO/TS 17137 and ISO/TR 37137.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 7198:2016, *Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137 (all parts), *Sterilization of health care products — Radiation*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*