Kardio-vaskulaarsed implantaadid. Veresoonesisesed vahendid. Osa 2: Stendid veresoontele

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2012)

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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English Version

Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539-2:2012)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 2: Endoprothèses vasculaires (ISO 25539-2:2012)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 2: Gefäßstents (ISO 25539-2:2012)

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Foreword

This document (EN ISO 25539-2:2012) 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of an identical text or by endorsement, at the latest by June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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 25539-2:2009.

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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

According to the CEN/CENELEC Internal Regulations, the national standards organisations 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 25539-2:2012 has been approved by CEN as a EN ISO 25539-2:2012 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

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC, Medical devices.

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 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.

Table ZA.1 — Correspondence between Directive 93/42/EEC and this European Standard

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
6,8,10 and 12	7.2	
6.3 and 7	7.3	
6	7.5 1st sentence	
6 and 7	7.6	
7	8.2	
12.1.5	8.3	
11.1	8.4	
11.2	8.5	
6 and 7	9.2, 2nd indent	
12.2.2	13.3 a)	
12.2.2	13.3 b)	
12.2.2	13.3 c)	
12.2.2	13.3 d)	
12.2.2	13.3 e)	
12.2.2	13.3 f)	
12.2.2	13.3 i)	
12.2.2	13.3 k)	
12.2.2	13.3 m)	
5	13.5	
12.3.2	13.6 g)	
12.3.2	13.6 k)	
12.3.2	13.6 q)	

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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Introduction

This part of ISO 25539 has been prepared in order to provide minimum requirements for endovascular devices and the methods of test that will enable their evaluation. It is the second part of a three-part standard. ISO 25539-1 addresses endovascular prostheses and ISO 25539-3 addresses vena cava filters. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements of this part of ISO 25539. The Technical Specification ISO/TS 15539 was developed by first identifying the design requirements for these devices and listing the potential device and clinical failure modes. Tests were then identified to address each of the failure modes. The requirements provided in this part of ISO 25539 are based on that assessment.

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Cardiovascular implants — Endovascular devices —

Part 2: Vascular stents

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1 Scope

1.1 This part of ISO 25539 specifies requirements for vascular stents, based upon current medical knowledge. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer. It should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

NOTE Due to the variations in the design of implants covered by this part of ISO 25539 and in some cases due to the relatively recent development of some of these implants (e.g. bioabsorbable stents, polymeric stents), acceptable standardized *in vitro* tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this part of ISO 25539 will be necessary.

1.2 The scope of this part of ISO 25539 includes vascular stents used to treat vascular lesions or stenoses, or other vascular abnormalities. These devices might or might not incorporate surface modifications of the stent such as drug and/or other coatings. Stents covered with materials that significantly modify the permeability of the uncovered stent are within the scope of ISO 25539-1. The stent design might dictate the need to address functional requirements identified in both ISO 25539-1 and this part of ISO 25539.

1.3 Delivery systems are included in this part of ISO 25539 if they comprise an integral component of the deployment of the vascular stent.

1.4 Procedures and devices used prior to the introduction of the vascular stent, such as balloon angioplasty devices, are excluded from the scope of this part of ISO 25539.

1.5 Some pharmacological aspects of drug-eluting stents are addressed in this part of ISO 25539, but this part of ISO 25539 is not comprehensive with respect to the pharmacological evaluation of drug-eluting stents.

1.6 Degradation and other time-dependent aspects of bioabsorbable and polymeric stents and coatings are not addressed by this part of ISO 25539.

1.7 With the exception of sterilization, this part of ISO 25539 does not address requirements for the evaluation of animal tissue products.

2 Normative references

The following referenced documents are indispensable for the application 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 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

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

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