SÜDAME-VERESOONKONNA IMPLANTAADID JA KEHAVÄLISED SÜSTEEMID. VASKULAARSE SEADME JA RAVIMI KOMBINATSIOONIS KASUTATAVAD TOOTED

Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements (ISO 12417-1:2015)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 12417-1:2015 sisaldab Euroopa standardi EN ISO 12417-1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 12417-1:2015 consists of the English text of the European standard EN ISO 12417-1:2015.
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 14.10.2015.	Date of Availability of the European standard is 14.10.2015.
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.

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English Version

Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements (ISO 12417-1:2015)

Implants cardiovasculaires et circuits extra-corporels - Produits de combinaison médicament-dispositif vasculaire - Partie 1: Exigences générales (ISO 12417-1:2015)

Kardiovaskuläre Implantate und extrakorporale Systeme - Vaskuläre Medizinprodukt/Arzneimittel-Kombinationsprodukte - Teil 1: Allgemeine Anforderungen (ISO 12417-1:2015)

This European Standard was approved by CEN on 8 August 2015.

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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 12417-1:2015 E

European foreword

This document (EN ISO 12417-1:2015) 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 April 2016, and conflicting national standards shall be withdrawn at the latest by April 2016.

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 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 12417-1:2015 has been approved by CEN as EN ISO 12417-1:2015 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

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 the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard 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.

This standard provides a process for managing risks associated with medical devices. Because this standard describes an ongoing process applicable in part or in all to the Essential Requirements of Directive 93/42/EEC on medical devices, it is not meaningful to link individual clauses of the standard to specific corresponding Essential Requirements.

Compliance with all the requirement clauses in this standard will ensure that general aspects of medical devices related to patient risk and safety have been addressed. For particular medical devices or for particular safety aspects, additional specific requirements may need to be complied with in order to meet the essential requirements. With respect to users of medical devices and third persons, additional specific requirements from other EU Directives may need to be complied with in order to meet Essential Requirement 1. Relevant harmonized standards may also be used for these purposes.

The risk management processes described in this standard could establish the need for collection of clinical or other experimental data for risk-benefit evaluation purposes. It does not describe how this has to be carried out. Relevant harmonized standards may be used for this purpose.

WARNING — Other requirements and other EU Directives may be applicable to a product falling within the scope of this 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 12417-1	Qualifying remarks
7.1	Clause 5 Clause 8	
7.2	Clause 8 9.3 Clause 10	
7.3	7.2.4.3 7.2.4.3.2 7.2.4.3.2 g) 7.2.4.3.5	

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 12417-1	Qualifying remarks
7.4	7.2.4.3 7.2.4.3.4 7.2.4.3.10 7.2.4.3.12 7.2.4.3.13	
7.5	7.2.4.3.4 7.2.4.3.10 7.2.4.3.11 7.2.4.3.16 9.3	
7.6	5.2.3 f)	
8.1	Clause 9 Clause 10	
8.3 (Design)	5.1 7.2.4.2	
8.3 (Manufacturing, Packaging)	Clause 8 Clause 9 10.1 10.2 11.2 m)	
8.4	9.1.1	
8.5	8.1 9.2	
8.6	9.2 Clause 10	
8.7	Clause 11	EN ISO 14630:2012, 11.2 f)
9.1	5.1 a) 5.2.3 e) 7.2.4.3.10	See specific standards product requirements for the device part
9.2 (Risk of injury)	5.1 7.2.4.1	
9.2 (Magnetic fields)	5.2.2 f) 5.2.3 g) 7.2.4.3.7	
9.2 (Aging)	5.2.1 e) 5.2.2 a) 7.1 7.2.4.3.10	
9.3	11.2.1 l)	

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/sub-clause(s) of this EN ISO 12417-1	Qualifying remarks
13.1	11.2.1 i) 11.3	
13.2	Clause 11	
13.3 a)	11.2.1 b)	
13.3 b)	11.2.1 a), c), d)	
13.3 c)	11.2.1 f)	
13.3 d)	11.2.1 e)	
13.3 e)	11.2.1 h)	
13.3 f)	11.2.1 g)	
13.3 i)	11.2.1 k)	
13.3 j)	11.2.1 i)	
13.3 k)	11.2.1 j)	
13.3 l)	11.2.1 l)	
13.3 m)	11.2.1 f)	
13.4	11.3 a), d)	
13.5	Clause 11	
13.6 a)	11.3	
13.6 b)	11.3 e), g), j), k), r)	
13.6 c)	N/A	See EN ISO 14630, 11.3 f)
13.6 e)	11.2 b), e), i), j), k), m)	
13.6 f)	11.3 j)	
13.6 g)	11.3 o), q)	
13.6 l)	11.3 j)	
13.6 m)	11.3 a), b), c), f)	
13.6 n)	11.3 k)	
13.6 q)	11.3 t)	

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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 WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

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

ISO 12417 consists of the following parts under the general title, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products*:

— *Part 1: General requirements*

— *Part 2: Local regulatory guidance*