MITTEAKTIIVSED KIRURGILISED IMPLANTAADID. ERINÕUDED SÜDAME- JA SOONTEIMPLANTAATIDELE. OSA 2: SOONTEPROTEESID, K.A SÜDAMEKLAPI SUISTIKUD

Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches (ISO 7198:2016)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 7198:2017 sisaldab Euroopa standardi EN ISO 7198:2017 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 7198:2017 consists of the English text of the European standard EN ISO 7198:2017.
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 01.03.2017.	Date of Availability of the European standard is 01.03.2017.
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.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 7198

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Supersedes EN 12006-2:1998+A1:2009

English Version

Cardiovascular implants and extracorporeal systems - Vascular prostheses - Tubular vascular grafts and vascular patches (ISO 7198:2016)

Implants cardiovasculaires et systèmes extracorporels - Prothèses vasculaires - Greffons vasculaires tubulaires et pièces vasculaires (ISO 7198:2016)

Kardiovaskuläre Implantate und extrakorporale Systeme - Vaskuläre Prothesen - Tubulare vaskuläre Transplantate und Gefäßpatches (ISO 7198:2016)

This European Standard was approved by CEN on 8 July 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

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

Ref. No. EN ISO 7198:2017 E

European foreword

This document (EN ISO 7198:2017) 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 12006-2:1998+A1:2009.

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 7198:2016 has been approved by CEN as EN ISO 7198:2017 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	ISO 10993-1:2009
	EN ISO 10993-2:2006	ISO 10993-2:2006
	EN ISO 10993-3:2014	ISO 10993-3:2014
	EN ISO 10993-4:2009	ISO 10993-4:2002 and ISO 10993-4:2002/Amd 1:2006
	EN ISO 10993-5:2009	ISO 10993-5:2009
	EN ISO 10993-6:2009	ISO 10993-6:2007
	EN ISO 10993-7:2008 and EN ISO 10993-7:2008/AC:2009	ISO 10993-7:2008 and ISO 10993-7:2008/Cor 1:2009
	EN ISO 10993-9:2009	ISO 10993-9:2009
	EN ISO 10993-10:2013	ISO 10993-10:2010
	EN ISO 10993-11:2009	ISO 10993-11:2006
	EN ISO 10993-12:2012	ISO 10993-12:2012
	EN ISO 10993-13:2010	ISO 10993-13:2010
	EN ISO 10993-14:2009	ISO 10993-14:2001
	EN ISO 10993-15:2009	ISO 10993-15:2000
	EN ISO 10993-16:2010	ISO 10993-16:2010
	EN ISO 10993-17:2009	ISO 10993-17:2002
	EN ISO 10993-18:2009	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	ISO 11137-1:2006 and ISO 11137-1:2006/Amd 1:2013
	EN ISO 11137-2:2015	ISO 11137-2:2013
	EN ISO 11137-3:2006	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 ISO 11607-1:2006/Amd 1:2014
ISO 14155	EN ISO 14155:2011 and EN ISO 14155:2011/AC:2011	ISO 14155:2011 and ISO 14155:2011/Cor. 1:2011

Normative references as listed in Clause 2	Equivalent dated standard	
	EN	ISO
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] 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 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 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.

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 Directive 93/42/EEC on medical devices

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
7.1, first indent	6.2 d), 6.3 d), 6.4 b) and c)	With respect to the first indent of ER 7.1, manufacturing is not covered by this standard. Toxicity and flammability are not covered by this standard. For tubular vascular grafts, the first indent of ER 7.1 is covered by 6.2 d). For vascular patches, the first indent of ER 7.1 is covered by 6.3 d). For coatings, the first indent of ER 7.1 is covered by 6.4 b) and c).
7.1, second indent	8.5.2, 8.6, 8.7	

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
7.2	Clause 12	Covered for design to protect patients from sterilization when the device is used. Manufacturing and packing to minimize these risks are not addressed.
8.1	Clause 12 and 13.5	Requirements are included for devices that are supplied sterile. Maintenance of sterility in transit is addressed. Minimizing contamination during use is not addressed. Risk of infection to the user and third party are not addressed.
8.3	Clauses 11, 12, 13	Sterility assurance, manufacturing, packaging design and maintenance of sterility are addressed.
8.4	Clauses 11, 12	Manufacturing, sterilization validation and routine control are addressed.
8.7	13.6.1 i)	
9.2, first indent	4.2, 8.7.2.3, 8.7.2.4, 8.7.3.3	Dimensions must be specified and dimensional verification required.
13.1	13.6	
13.3 a)	13.6.1	The standard does not address the requirement regarding the authorized representative where the manufacturer does not have a registered place of business in the Community.
13.3 b)	13.6.1 b), c), d), e), f), g)	ER 13.3 b) is only satisfied in respect of the information specified in the standard clauses.
13.3 c)	13.6.1 i)	ER 13.3 c) is only satisfied if the word "STERILE" (or the harmonized symbol) is used.
13.3 d)	13.6.1 k)	Only covered if the batch code is preceded by the word LOT.
13.3 e)	13.6.1 m)	ER 13.3 e) is only satisfied if the expiration date in the format year and month is given.
13.3 f)	13.6.1 i)	Consistency of marking across the community is not covered.
13.3 i)	13.6.1 o)	Covered for storage instructions.
13.3 k)	13.6.1 n)	ER 13.3 k) is only satisfied in respect of damage to the packaging.

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Remarks/Notes
13.3 m)	13.6.1 j)	
13.6 a)	13.6.3 b), 13.6.3 c), 13.6.3 d), 13.6.3 f)	Covered for the items listed in 13.3 c), f), i) (handling is not covered), j), and k). Note: • 13.3 c) is covered by 13.6.3 d), • 13.3 f) is covered by 13.6.3 d), • 13.3 i) is covered by 13.6.3 f), • 13.3 j) is covered by 13.6.3 c) • 13.3 k) is covered by 13.6.3 b)
13.6 b)	13.6.3 a), b)	Performance is not covered.
13.6 c)	13.6.3 c)	Methods for preparation and implantation techniques. Use of endovascular systems involve use of additional medical devices (e.g. syringes, wire guides).
13.6 d)	13.6.3 c)	First part covered (installation and preparation for operation only).
13.6 i)	13.6.3 c)	
13.6 q)	13.6.3 g)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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