BS EN ISO 7198:2017

BSI Standards Publication

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

bsi.

This British Standard is the UK implementation of EN ISO 7198:2017. it is identical to ISO 7198:2016. It supersedes BS ISO 7198:1998 and BS EN 12006-2:1998+A1:2009 which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its secretary.

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EUROPEAN STANDARD **EN ISO 7198**

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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.

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

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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of an identical text or by endorsement, at the latest by September 2017, and conflicting national standards shall be withdrawn at the latest by March 2020.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.

Contents

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*.

This second edition cancels and replaces the first edition (ISO 7198:1998), which has been technically revised.

Introduction

This International Standard has been prepared in order to provide minimum requirements for tubular vascular grafts and vascular patches, including guidance on the methods of test that will enable their evaluation. This International Standard is an update of ISO 7198:1998, necessary given the introduction of new standards for endovascular prostheses, vascular stents and vascular device-drug combination products.

This International Standard covers vascular prostheses implanted using direct visualization surgical techniques as opposed to fluoroscopic or other non-direct imaging (e.g. computerized tomography or magnetic resonance imaging). ISO 25539-1 specifies requirements and testing guidelines for endovascular prostheses, implanted using catheter delivery and non-direct visualization. Since the design of endovascular prostheses often involves the use of materials that are used in traditional vascular prostheses, some of the methods to evaluate these materials are contained in this International Standard and referenced in the endovascular prostheses standard (ISO 25539-1).

It is recognized by this ISO committee that many forms of tubular vascular grafts and vascular patches have been shown to be a safe and effective means to surgically restore blood flow in various indications over many years. This update is not intended to significantly change the manner in which tubular vascular grafts have been evaluated or to add new requirements. Therefore, manufacturers can rely on evaluation and historical data gathered under ISO 7198:1998 to meet the requirements that have not changed in the current standard. The committee recognizes that, with the addition of requirements for vascular patches and references to device-drug combination requirements in other ISO documents, a reasonable amount of time (e.g. one to three years) might be needed to become fully compliant with this International Standard.

INTERNATIONAL STANDARD ISO 7198:2016(E)

Cardiovascular implants and extracorporeal systems — Vascular prostheses — Tubular vascular grafts and vascular patches

1 Scope

1.1 This International Standard specifies requirements for the evaluation of vascular prostheses 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 International Standard. This International Standard can be considered as a supplement to ISO 14630:2012, 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 International Standard and, in some cases, due to the relatively recent development of some of these implants (e.g. bioabsorbable vascular prostheses, cell based tissue engineered vascular prostheses), acceptable standardized *in vitro* tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this International Standard will be necessary.

1.2 This International Standard is applicable to sterile tubular vascular grafts implanted by direct visualization surgical techniques as opposed to fluoroscopic or other non-direct imaging (e.g. computerized tomography or magnetic resonance imaging), intended to replace, bypass, or form shunts between segments of the vascular system in humans and vascular patches intended for repair and reconstruction of the vascular system.

1.3 Vascular prostheses that are made of synthetic textile materials and synthetic non-textile materials are within the scope of this International Standard.

1.4 While vascular prostheses that are made wholly or partly of materials of non-viable biological origin, including tissue engineered vascular prostheses are within the scope, this International Standard does not address sourcing, harvesting, manufacturing and all testing requirements for biological materials. It is further noted that different regulatory requirements might exist for tissues from human and animal sources.

1.5 Compound, coated, composite, and externally reinforced vascular prostheses are within the scope of this standard.

1.6 Endovascular prostheses implanted using catheter delivery and non-direct visualization are excluded from the scope of this International Standard. This International Standard includes information on the development of appropriate test methods for graft materials, referenced in ISO 25539-1 for materials used in the construction of endovascular prostheses (i.e. stent-grafts).

NOTE Requirements for endovascular prostheses are specified in ISO 25539-1.

1.7 The valve component of valved conduits constructed with a tubular vascular graft component, and the combination of the valved component and the tubular vascular graft component, are excluded from the scope of this International Standard. This International Standard can be helpful in identifying the appropriate evaluation of the tubular vascular graft component of a valved conduit but specific requirements and testing are not described for these devices.