BRITISH STANDARD

BS EN
12006-2:1998

Non-active surgical implants — Particular requirements for cardiac and vascular implants —

Part 2: Vascular prostheses including cardiac valve conduits

The European Standard EN 12006-2:1998 has the status of a British Standard

ICS 11.040.40

National foreword

This British Standard is the English language version of EN 12006-2:1998.

The UK participation in its preparation was entrusted to Technical Committee CH/23, Cardiovascular implants, dialysis systems and oxygenators, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

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

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the BSI Standards Catalogue under the section entitled "International Standards Correspondence Index", or by using the "Find" facility of the BSI Standards Electronic Catalogue.

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Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 7 and a back cover.

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EUROPEAN STANDARD
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Descriptors: Medical equipment, surgical implants, vascular prostheses, definitions, physical properties, mechanical properties, chemical properties, dimensions, tests, packing, labelling, information, classifications

English version

Non-active surgical implants — Particular requirements for cardiac and vascular implants — Part 2: Vascular prostheses including cardiac valve conduits

Implants chirurgicaux non actifs — Exigences particulières pour les implants cardio-vasculaires — Partie 2: Prothèses vasculaires y compris les conduits valvulés

Nichtaktive chirurgische Implantate — Besondere Anforderungen für Herz- und Gefäßimplantate — Teil 2: Gefäßprothesen, einschließlich Herzklappen-Gefäßstutzen

This European Standard was approved by CEN on 16 January 1998.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 12006-2:1998 E

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 285, Non-active surgical implants, the secretariat of which is held by NNI.

This European Standard 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 standard.

There are three levels of European Standards dealing with non-active surgical implants. These are as follows, with level 1 being highest.

Level 1: *General requirements for non-active surgical implants.*

Level 2: *Particular requirements for families of non-active surgical implants.*

Level 3: *Specific requirements for types of non-active surgical implants.*

This is a level 2 standard and contains requirements that apply to non-active surgical implants in the family of vascular prostheses, including cardiac valve conduits.

The level 1 standard contains requirements that apply to all non-active surgical implants. It also indicates that there are additional requirements in the level 2 and level 3 standards. The level 1 standard has been published as EN ISO 14630:1997.

Level 3 standards apply to specific types of implants within a family such as bone plates and hip joints. To address all requirements, it is recommended to start with a standard of the lowest available level.

References to other European or international standards can also be found in annex B "Bibliography".

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 August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Contents

Introduction

This European Standard provides, in addition to the requirements in EN ISO 14630:1997, a method to demonstrate compliance with the relevant Essential Requirements as outlined in general terms in annex 1 of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to vascular prostheses including cardiac valve conduits.

It should be read in conjunction with EN ISO 14630:1997. In addition to the requirements of EN ISO 14630:1997, this European Standard is, for a major part, based on ISO/DIS 7198. Furthermore, it gives requirements not given in EN ISO 14630:1997 or ISO/DIS 7198.

1 Scope

This standard describes specific requirements for vascular prostheses, including cardiac valve conduits, of synthetic or biological origin intended to replace, to reconstruct, to bypass or to form shunts between segments of the cardio-vascular system in humans. This European Standard is not applicable to prostheses derived from host tissue (autografts).

NOTE A valve conduit is regarded as a composite prosthesis and falls within the scope of this standard.

With regard to safety it gives, in addition to EN ISO 14630:1997, requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

This European Standard specifies the designation of materials of the manufacturer and the construction of the device, and the designation of sizes and dimensions of vascular prostheses. It specifies biological requirements for the materials of construction and for the finished product by references to appropriate international and European Standards.

In addition, this European Standard specifies the designation of mechanical properties. It describes methods for the measurement and verification of the dimensions and mechanical properties stated by the manufacturer, including durability testing.

This standard also gives requirements for packaging and labelling. It provides definitions of the terms in common use.

This European Standard does not specify all possible performance or dimensional characteristics. In such cases, the European Standard does, however, include methods to verify the nominal values stated by the manufacturer.

2 Normative references

This European Standard incorporates, by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

prEN 12006-1, *Non-active surgical implants — Particular requirements for cardiac and vascular implants — Part 1: Heart valve substitutes.*

EN ISO 14630:1997, *Non-active surgical implants — General requirements.* (ISO 14630:1997)

ISO/DIS 7198, *Cardiovascular implants — Tubular vascular prostheses.*

NOTE 1 Annex B gives informative references to other useful standards.

NOTE 2 This standard refers to many items of ISO/DIS 7198. In order to keep the European and the future international standard aligned, the table in the informative annex C indicates, for a clause of this European Standard, where the text of a requirement can be found in the corresponding ISO/DIS 7198.

3 Definitions

For the purposes of this European Standard the definitions in EN ISO 14630:1997 and ISO/DIS 7198 apply together with the following:

3.1

kink radius

radius of curvature at which kinking of a vascular prosthesis commences

NOTE The definition of leakage differs from the definition in EN ISO 14630:1997, due to the intended purpose of the device covered by this standard.

4 Intended performance

The requirements of clause **4** of EN ISO 14630:1997 apply, together with the following.

The intended clinical use shall be designated in accordance with ISO/DIS 7198 (see also annex C).

Manufacturers shall record the intended conditions of, or restrictions on, use of the implant, together with instructions for presentation and preparation before implantation.

5 Design attributes

The requirements of clause **5** of EN ISO 14630:1997 apply, together with the following.

The configuration and size designation shall be described in accordance with ISO/DIS 7198 (see annex C).

Prostheses shall be classified in accordance with annex A.

6 Materials

The requirements of clause **6** of EN ISO 14630:1997 apply, together with the following.

6.1 Biocompatibility and biostability

Testing of biocompatibility and biostability of materials shall comply with ISO/DIS 7198 (see also annex C).

6.2 Chemical properties — nomenclature

For synthetic materials, biological materials, coatings, storage fluids and residual chemicals, the appropriate clauses of ISO/DIS 7198 apply (see annex C).

7 Design evaluation

The requirements of clause **7** of EN ISO 14630:1997 apply, together with the following.

7.1 Functional characteristics

7.1.1 *Compound prostheses*

For compound prostheses constructed of a permeable base to which a coating has been applied in order to reduce water permeability of the implantable state, the following shall be determined:

a) water permeability of the base prostheses before the application of the coating;

b) integral water permeability of the prostheses in the implantable state;

and tested in accordance with **7.4**.

7.1.2 *Composite prosthesis*

For a composite prosthesis that consists of two or more vascular prosthetic segments joined by manufactured anastomoses the following apply:

a) all segments shall comply with the requirements of the appropriate clauses of this standard;

b) all manufactured anastomoses shall comply with the requirements for integral water permeability and leakage [**7.2**a)] and the requirements for strength [**7.2**b)].

7.1.3 *Composite cardio-vascular prosthesis (valve conduit)*

For a composite prosthesis that consists of one or more vascular prosthetic segments and a cardiac valve prosthesis the following apply:

a) all vascular prosthetic segments shall comply with the requirements of the appropriate clauses of this standard;

b) all cardiac valve prostheses shall comply with prEN 12006-1;

c) all manufactured anastomoses shall comply with the requirements for integral water permeability and leakage [see **7.2**a)] and the requirements for strength [see **7.2**b)].

7.2 Requirements for finished prosthesis

The following shall conform to the requirements of ISO/DIS 7198 (see annex C):

a) porosity, water permeability, integral water permeability/leakage, water entry;
b) strength;
c) length;
d) relaxed internal diameter;
e) pressurized internal diameter;
f) wall thickness;
g) suture retention strength;
h) kink diameter/radius;
i) compliance.

7.3 Sampling

Sampling for characterization and sampling for quality control shall be performed in accordance with ISO/DIS 7198 (see annex C).

7.4 Test methods

The following shall be evaluated in accordance with ISO/DIS 7198 (see annex C):

a) visual inspection;
b) determination of porosity, water permeability, integral water permeability/leakage, and water entry pressure;
c) determination of strength;
d) determination of usable length;
e) determination of relaxed internal diameter;
f) determination of pressurized diameter;
g) determination of wall thickness;
h) determination of suture retention strength;
i) determination of kink diameter/radius;
j) determination of dynamic compliance.

7.5 In vivo pre-clinical evaluation

In vivo pre-clinical evaluation shall be performed in accordance with ISO/DIS 7198 (see annex C).

7.6 Clinical evaluation

Trial design, data acquisition and data analysis for in vivo clinical evaluation shall be performed in accordance with ISO/DIS 7198 (see annex C).

7.7 Test reports

Test reports shall conform to the requirements of ISO/DIS 7198 (see annex C).

8 Manufacturing

The requirements of clause **8** of EN ISO 14630:1997 apply.

The surface properties shall be inspected in accordance with ISO/DIS 7198 (see annex C).

9 Sterilization

The requirements of subclauses **9.1** and **9.3** of EN ISO 14630:1997 apply.

10 Packaging

The requirements of clause **10** of EN ISO 14630:1997 apply.

The requirements for the unit, outer and shipping container of ISO/DIS 7198 apply (see annex C).

11 Information supplied by the manufacturer

The requirements of clause **11** of EN ISO 14630:1997 apply.

In addition, the requirements for general information and instructions for use and the requirements for marking of ISO/DIS 7198 apply (see annex C).

Annex A (normative)

Classification of prostheses

Each prosthesis shall be classified as indicated below:

a) synthetic textile:
   1) knitted;
   2) woven;

b) synthetic non-textile:
   1) extruded/expanded polymers;
   2) other(s) (specify);

c) biological:
   1) allograft;
   2) xenograft;

d) compound prosthesis;

e) composite prosthesis.

Annex B (informative)

Bibliography

ANSI/ASTM D1503-68, *Test for density of plastics by the density gradient technique.*

EN ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals.* (ISO 10993-7:1995)

EN 540, *Clinical investigation of medical devices for human subjects.*

Eur.P: 1996, *European Pharmacopoeia*, 3rd Edition.

ISO 472, *Plastics — Vocabulary.*

ISO 2076, *Textiles — Man-made fibres — Generic names.*

ISO 2859-1, *Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level for lot-by-lot inspection.*

ISO 2859-2, *Sampling procedures and tables for inspection by attributes — Part 2: Sampling plans indexed by limiting quality (LQ) for isolated lot inspection.*

ISO 2960, *Textiles — Determination of bursting strength and bursting distension — Diaphragm method.*

ISO 5081, *Textiles — Woven fabrics — Determination of breaking strength and elongation (Strip method).*

ISO 5084, *Textiles — Determination of thickness of textiles and textile products.*

USP:1995, *United States Pharmacopoeia*, 23rd Edition.

Annex C (informative)
Reference table EN 12006-2 and ISO/DIS 7198

The left part of the table lists clauses of the prEN; the right part of the table indicates those ISO/DIS 7198 clauses which address the same requirement. In the normative text, references are made in general to this table. The table lists the relevant clauses in ISO/DIS 7198 that are applicable. When the ISO standard is revised, the table will be updated.

The clause numbering of ISO/DIS 7198 is based on the 1996 edition.

Table C.1

EN 12006-2	Heading	ISO/DIS 7198:1996	Heading
4	Intended performance	**4.2**	Intended clinical use application
5	Design attributes	**4.1**	Configuration and size designation
6	Materials		
6.1	Biocompatibility and biostability	**4.4.1**	Biocompatibility
		4.4.2	Biostability
6.2	Chemical properties — nomenclature	**4.3.2**	Materials and construction — nomenclature
7.2	Requirements for finished prosthesis	**5**	Requirements for finished prosthesis
		5.2	Porosity, water permeability, integral water permeability/leakage, water entry
		5.3	Strength
		5.4	Length
		5.5	Relaxed internal diameter
		5.6	Pressurized internal diameter
		5.7	Wall thickness
		5.8	Suture retention strength
		5.9	Kink diameter/radius
		5.10	Compliance
7.3	Sampling	**7**	Sampling
		7.1	Sampling for characterization
		7.2	Sampling for quality control
7.4	Test methods	**8**	Test methods for vascular prosthesis.
		8.1	Visual inspection
		8.2	Determination of porosity, water permeability, integral water permeability/leakage, and water entry pressure
		8.3	Determination of strength
		8.4	Method for determination of usable length
		8.5	Method for determination of relaxed internal diameter
		8.6	Method for determination of pressurized diameter
		8.7	Method for determination of wall thickness
		8.8	Method for determination of suture retention strength

Table C.1 *(continued)*

EN 12006-2	Heading	ISO/DIS 7198:1996	Heading
		8.9	Method for determination of kink diameter/radius
		8.10	Method for determination of dynamic compliance
7.5	In vivo pre-clinical evaluation	**6.1**	In vivo pre-clinical testing
		9.1	Method for trial design, etc.
7.6	Clinical evaluation	**6.2**	Clinical evaluation
		9.2	Method for trial design, etc.
7.7	Test reports	**4.9.1**	Test reports — General requirements
		4.9.2	Additional information
8	Manufacturing	**5.1**	Visual inspection
10	Packaging	**4.7**	Packaging
		4.7.1	Unit container
		4.7.2	Outer container
		4.7.3	Shipping container
11	Information supplied by the manufacturer	**4.6**	General information and instructions for use
		4.8	Marking-container label and record label

Annex ZA (informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives.

This European Standard 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 93/42/EEC of 14 June 1993 concerning medical devices.

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

The clauses for this standard, as detailed in Table ZA.1, are likely to support requirements of Council Directive 93/42/EEC.

Compliance with the clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1

Clauses/subclauses of this European Standard	Corresponding annex/paragraph of Directive 93/42/EEC	Remarks
4, **5**, **6**, **7**, **8**, **9**, **10**, **11**	Annex **1**: **1**, **2**, **3**, **4**, **5**, **6**, **7.1**, **7.2**, **7.3**, **7.4**, **8.1**, **8.2**, **8.3**, **8.4**, **8.5**, **9.1**, **9.2**, **13**, **14**	

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