# SLOVENSKI STANDARD
# SIST EN 12006-2:2000

**01-januar-2000**

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**Neaktivni kirurġki vsadki (implantati) - Posebne zahteve za srļ noģilne vsadke (kardiovaskularne implantate) - 2. del: Ģilne proteze, vkljuļ no s cevastimi vsadki s srļ nimi zaklopkami (tubularnimi grafti)**

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

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



Implants chirurgicaux non actifs - Exigences particulieres pour les implants cardio-vasculaires - Partie 2: Protheses vasculaires y compris les conduits valvulés



**Ta slovenski standard je istoveten z:** **EN 12006-2:1998**

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**ICS:**

| | | |
|---|---|---|
| 11.040.40 | Implantanti za kirurgijo, protetiko in ortetiko | Implants for surgery, prosthetics and orthotics |

**SIST EN 12006-2:2000** **en**

# EUROPEAN STANDARD
# NORME EUROPÉENNE
# EUROPÄISCHE NORM

# EN 12006-2

February 1998

ICS 11.040.40

Descriptors: medical equipment, surgical implants, vascular protheses, definitions, physical properties, mechanical properties, chemical properties, dimensions, tests, packing, labelling, informations, 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

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

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 Central Secretariat 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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.



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

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

**Contents**

**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.

**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 the 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 gives also 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.



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|---|---|
| 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 at 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 protheses 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 clause 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 anastomosis shall comply with the requirements for integral water permeability and leakage (7.2a)) and the requirements for strength (see clause 7.2b)).

**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 prosthesis shall comply with prEN 12006-1;

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

**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