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NSAI Standards

Irish Standard
I.S. EN 12006-2:1998+A1:2009

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 12006-2:1998+A1

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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

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Foreword

This document (EN 12006-2:1998+A1:2009) has been prepared by 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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

This document includes Amendment 1, approved by CEN on 2009-04-05.

This document supersedes EN 12006-2:1998.

The start and finish of text introduced or altered by amendment is indicated in the text by tags A1 A1.

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".

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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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.

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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 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:

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