Mitteaktiivsed kirurgilised implantaadid. Erinõuded südame ja veresoonkonna implantaatidele. Osa 1: Südameklapi asendajad

Non-active surgical implants - Particular requirements for cardiac and vascular implants - Part 1: Heart valve substitutes

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 12006-1:2000 sisaldab Euroopa standardi EN 12006-1:1999 ingliskeelset teksti. Käesolev dokument on jõustatud 11.01.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12006-1:2000 consists of the English text of the European standard EN 12006-1:1999. This document is endorsed on 11.01.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This Standard specifies particular requirements for heart valve substitutes. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing and inspection, sterilization, packaging and information supplied by the manufacturer.	**Scope:** This Standard specifies particular requirements for heart valve substitutes. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing and inspection, sterilization, packaging and information supplied by the manufacturer.

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Non-active surgical implants

Particular requirements for cardiac and vascular implants

Part 1: Heart valve substitutes

Implants chirurgicaux non actifs – Exigences particulières pour les implants cardio-vasculaires – Partie 1: Prothèses valvulaires cardiaques

Nichtaktive chirurgische Implantate – Besondere Anforderungen für Herz- und Gefäßimplantate – Teil 1: Herzklappenprothesen

This European Standard was approved by CEN on 1999-06-19.

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.

The European Standards exist 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.

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CEN

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

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

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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 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2000, and conflicting national standards shall be withdrawn at the latest by January 2000.

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 I being the 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 standard is a level 2 standard and contains requirements that apply to all non-active surgical implants in the family of heart valve substitutes.

The level 1 standard, EN ISO 14630:1997, contains requirements that apply to all non-active surgical implants.

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.

Working group 3 "Cardiac Vascular Implants" of CEN/TC 285 collaborated closely with the International Organization for Standardization (ISO/TC 150) in order to come to a standard for Heart Valve Substitutes, which is as harmonized as possible. The table at the informative Annex G indicates for each EN 12006-1 clause, whether the requirements are covered by compliance with the corresponding ISO 5840 clause.

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 cardiac and vascular implants - heart valve substitutes.

1 Scope

This standard specifies particular requirements for heart valve substitutes.

This European Standard is not applicable to heart valve substitutes composed in whole, or in part, of human tissue.

With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

This European Standard specifies a number of test methods and requirements regarding the performance characteristics of equipment to be used to determine the physical, biological and chemical properties of heart valve substitutes and of the materials and components of which they are made.

Recommendations are also made for *in vivo* testing and clinical evaluation, and for the reporting of results of all types of testing and evaluation covered in this European Standard. These recommendations do not purport to comprise a complete test programme (see annex F for rationale).

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.

EN ISO 14630:1997	Non-active surgical implants - General requirements (ISO 14630:1997)
EN ISO 10993-1:1997	Biological evaluation of medical devices - Part 1: Evaluation and testing (ISO 10993-1:1997)
ISO 5840	Cardiovascular implants - Cardiac valve prostheses

3 Definitions

For the purposes of this standard the definitions given in EN ISO 14630:1997 apply together with the following:

3.1 anticoagulant-related haemorrhage: Internal or external bleeding that causes death or stroke, or that requires transfusion, operation or hospitalization [ISO 5840].