# Mitteaktiivsed kirurgilised implantaadid. Erinõuded südame- ja soonteimplantaatidele. Osa 3: Soonesisesed vahendid KONSOLIDEERITUD TEKST

Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices CONSOLIDATED TEXT

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

## EESTI STANDARDI EESSÕNA

## NATIONAL FOREWORD

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|---|---|
| Käesolev Eesti standard EVS-EN 12006-3:1999+A1:2009 sisaldab Euroopa standardi EN 12006-3:1998+A1:2009 ingliskeelset teksti. | This Estonian standard EVS-EN 12006-3:1999+A1:2009 consists of the English text of the European standard EN 12006-3:1998+A1:2009. |
| Standard on kinnitatud Eesti Standardikeskuse 30.06.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas. | This standard is ratified with the order of Estonian Centre for Standardisation dated 30.06.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation. |
| Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 06.05.2009. | Date of Availability of the European standard text 06.05.2009. |
| Standard on kättesaadav Eesti standardiorganisatsioonist. | The standard is available from Estonian standardisation organisation. |



**ICS** 11.040.40

**Võtmesõnad:** filtrid, kirurgilised implantaadid, konstruktsioon, korrosioonikindlus, materjalid, meditsiiniaparatuur, meditsiiniseadmed, mõõtmed, soonesulgurid, steriliseerimine, südameklapid, tehnilised andmed, tootmine, tööiga väsimuse tekkeni

EUROPEAN STANDARD

NORME EUROPÉENNE

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English Version

# Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices

Implants chirurgicaux non-actifs - Exigences particulières pour les implants cardio- vasculaires - Partie 3: Dispositifs endovasculaires

Nichtaktive chirurgische Implantate - Besondere Anforderungen an Herz- und Gefäßimplantate - Teil 3: Endovaskuläre Implantate

This European Standard was approved by CEN on 8 November 1998 and includes Amendment 1 approved by CEN on 5 April 2009.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

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# Foreword

This document (EN 12006-3:1998+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 12006-3:1998.

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).

⟨A1⟩ For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard. ⟨A1⟩

There are three levels of European Standards dealing with non-active surgical implants. These are as follows, with level 1 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 vena cava filters and vascular stents.

The level 1 standard contains requirements that apply to all non-active surgical implants.

Level 3 standards contain requirements that apply to specific types of implants within a family.

To address all requirements, it is necessary to start with a standard of the lowest available level.

References can also be found in Annex A of this standard.

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.

## Introduction

This European Standard in addition to EN ISO 14630 provides 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 endovascular devices.

## 1 Scope

This European Standard specifies particular requirements for endovascular devices.

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

NOTE 1 Vascular occluders are not addressed in this standard. For the time being the requirements as stated in EN ISO 14630:1997 apply for these products.

NOTE 2 Due to the variations in the design of the implants covered by this standard and in some cases due to the relatively recent development of some of these implants, acceptable standardized in vitro tests and long term results of clinical trials are not always available.

Where no test method is described in this standard a complete description of the validated test method and sample preparation procedure used should be documented by the manufacturer. With regard to design evaluation, where a specific standardized test is not described, guidance is given by referring to current scientific literature (see Annex A). This standard aims to ensure that manufacturers will address all aspects of design evaluation that relate to the safety of the product. As further scientific and clinical data become available, appropriate revision of the standard will be necessary.

## 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)*

ISO 10555-4, *Sterile, single-use intravascular catheters – Part 4: Balloon dilatation catheters*

## 3 Definitions

For the purpose of this standard the definitions of EN ISO 14630 apply together with the following:

**3.1**
**vascular stent**
implantable expandable tubular structure supporting a vascular conduit

**3.2**
**vena cava filter**
implantable expanding filtering device to be inserted into the vena cava

**3.3**
**stented graft**
a combination of one or more stents and a tubular graft

## 4 Intended performance

The requirements of clause 4 of EN ISO 14630:1997 apply.