

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

Part 3: Endovascular devices

ICS 11.040.40

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National foreword

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The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to CEN text carry the number of the CEN amendment. For example, text altered by CEN amendment A1 is indicated by **A1** **A1**.

The UK participation in its preparation was entrusted to Technical Committee CH/50, Implants for surgery, to subcommittee CH/150/2, Cardiovascular implants.

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

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This British Standard, having been prepared under the direction of the Health and Environment Sector Committee, was published under the authority of the Standards Committee and comes into effect on 15 March 1999

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Amendments/corrigenda issued since publication

Date	Text affected
31 December 2009	Implementation of CEN amendment A1:2009; alignment of BSI and CEN publication dates

ISBN 978 0 580 65158 8

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.

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Contents

Page

Foreword.....	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Definitions	5
4 Intended performance	5
5 Design attributes.....	6
6 Materials	6
7 Design evaluation	6
8 Manufacturing	9
9 Sterilization.....	9
10 Packaging	9
11 Information supplied by the manufacturer	9
Annex A (informative) Bibliography	10
Annex B (informative) Animal studies with stents.....	12
Annex ZA (informative)  Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC 	14

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.