SLOVENSKI STANDARD
SIST EN 12006-2:2000/kprA1:2009

01-marec-2009

Neaktivni kirurġki vsadki (implantati) - Posebne zahteve za srļ noģilne vsadke (kardiovaskularne implantate) - 2. del: Ģilne proteze, vključļ 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 particulières relatives aux implants cardiaques et vasculaires - Partie 3: Dispositifs endovasculaires

Ta slovenski standard je istoveten z: **EN 12006-2:1998/prA1**

ICS:

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

SIST EN 12006-2:2000/kprA1:2009 **en,fr**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
EN 12006-2:1998

prA1

December 2008

ICS 11.040.40

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

This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/TC 285.

This draft amendment A1, if approved, will modify the European Standard EN 12006-2:1998. If this draft becomes an amendment, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration.

This draft amendment was established by CEN 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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Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Foreword

This document (EN 12006-2:1998/prA1:2008) has been prepared by Technical Committee CEN/TC 285 “Non-active surgical implants”, the secretariat of which is held by DIN.

This document is currently submitted to the Unique Acceptance Procedure.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, which is an integral part of this document.

1 Modification to Annex ZA

Replace the existing Annex ZA with the following:

"

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4, 5, 6, 7, 8, 9, 10, 11	Annex 1: 1, 2, 3, 4, 5, 6, 6a., 7.1, 7.2, 7.3, 7.4, 8.1, 8.2, 8.3, 8.4, 8.5, 9.1, 9.2, 13	The part of ER 7.4 relating to the regulatory provision for the verification of the medicinal product is not addressed in this European Standard. Part of ER 13.3 f relating to single use is not addressed in this European Standard. Part of ER 13.3 a) relating to the authorised representative is not addressed. Part of ER 13.6 h) relating to single use is not addressed in this European Standard. Part of ER 13.6 q) relating to the date of issue of the instructions for use is not addressed in this European Standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard."