SLOVENSKI STANDARD
SIST EN ISO 9713:2004

01-oktober-2004

Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2002)

Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2002)

Neurochirurgische Implantate - Selbstschließende intrakranielle Aneurysmen-Clips (ISO 9713:2002)

Implants neurochirurgicaux - Clips intracrâniens pour anévrisme a autofermeture (ISO 9713:2002)

Ta slovenski standard je istoveten z: **EN ISO 9713:2004**

ICS:

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

SIST EN ISO 9713:2004 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 9713

February 2004

ICS 11.040.40

English version

Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2002)

Implants neurochirurgicaux - Clips intracrâniens pour anévrisme à autofermeture (ISO 9713:2002)

Neurochirurgische Implantate - Selbstschließende intrakranielle Aneurysmen-Clips (ISO 9713:2002)

This European Standard was approved by CEN on 2 January 2004.

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.

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 Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

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

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Ref. No. EN ISO 9713:2004: E

Foreword

The text of ISO 9713:2002 has been prepared by Technical Committee ISO/TC 150/SC 3 "Neurosurgical implants" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 9713:2004 by Technical Committee CEN/TC 285 "Non-active surgical implants", the secretariat of which is held by NEN.

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 August 2004, and conflicting national standards shall be withdrawn at the latest by August 2004.

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 EU Directive(s).

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

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO 9713:2002 has been approved by CEN as EN ISO 9713:2004 without any modifications.

NOTE Normative references to International Standards are listed in annex ZA (normative).

Annex ZA
(normative)

Normative references to international publications with their relevant European publications

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 (including amendments).

NOTE Where an International Publication has been modified by common modifications, indicated by (mod.), the relevant EN/HD applies.

Publication	Year	Title	EN	Title	Year
ISO 14630	1997	Non-active surgical implants - General requirements	EN ISO 14630	Non-active surgical implants - General requirements (ISO 14630:1997)	1997
ISO 15223	2000	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied	EN 980	Graphical symbols for use in the labelling of medical devices	1996
			EN 1041	Information supplied by the manufacturer with medical devices	1998
ISO 16061	2000	Instrumentation for use in association with non-active surgical implants - General requirements	EN 12011	Instrumentation to be used in association with non-active surgical implants - General requirements	1998

Annex ZB
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

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 93/42/EEC of 14 June 1993 concerning medical devices.

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

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZB.1— Correspondence between this European Standard and EU Directives

Clauses/subclauses of this European Standard	Essential requirements (ERs) of Directive 93/42/EEC
5	1, 2, 3, 9.2
6	1, 2, 7.1, 7.3, 9.2
7	6, 9.2
8	3, 4,
9	13.1, 13.3
10	1, 5, 7.2, 8.1, 8.3, 8.4, 8.5
11	5, 8.6, 8.7, 13.1
12	8.7, 13.1, 13.2, 13.3, 13.4,13.6

INTERNATIONAL STANDARD

ISO 9713

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Neurosurgical implants — Self-closing intracranial aneurysm clips

Implants neurochirurgicaux — Clips intracrâniens pour anévrisme à autofermeture

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