# SLOVENSKI STANDARD

**SIST EN ISO 7197:2006**

**01-julij-2006**

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**Nevrokirurški vsadki (implantati) - Sterilni hidrocefalni stiki (kretnice) za enkratno uporabo in komponente (ISO 7197:2006)**

Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006)

Neurochirurgische Implantate - Sterile Hydrozephalus-Shunts zum Einmalgebrauch und deren Bestandteile (ISO 7197:2006)



Implants neurochirurgicaux - Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie (ISO 7197:2006)



**Ta slovenski standard je istoveten z:** **EN ISO 7197:2006**

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**ICS:**

11.040.40

**SIST EN ISO 7197:2006** **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 7197

June 2006

ICS 11.040.40

English Version

## Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006)

Implants neurochirurgicaux - Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie (ISO 7197:2006)

Neurochirurgische Implantate - Sterile Hydrozephalus-Shunts zum Einmalgebrauch und deren Bestandteile (ISO 7197:2006)

This European Standard was approved by CEN on 19 May 2006.

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, Romania, 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 7197:2006: E

## Foreword

This document (EN ISO 7197:2006) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with 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 December 2006, and conflicting national standards shall be withdrawn at the latest by December 2006.

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 ZA, 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, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



**Endorsement notice**

The text of ISO 7197:2006 has been approved by CEN as EN ISO 7197:2006 without any modifications.

# 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 to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC of 14 June 1993 concerning 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.1 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.1 — Correspondence between this European Standard and Directive 93/42/EEC**

| Clause(s)/Sub-clause(s) of this European Standard | Essential Requirements (ERs) of EU Directive 93/42/EEC | Qualifying remarks/Notes |
|---|---|---|
| All | 1, 2, 3, 4, 5 | |
| 4.2 | 2 | |
| 4.3 | 7.1, 7.2 | |
| 4.4 | 7.5 | |
| 4.5 | 3, 4, 13.6.d) | |
| 4.6 | 3, 4, 9.1 | |
| 4.7 | 2, 13.6.d), 13.6.e) | |
| 4.8 | 4, 9.2, 12.7.1 | |
| 4.9 | 12.7.1 | |
| 4.10 | 9.1, 9.2 | |
| 4.11 | 12.7.1 | |
| 5.1.1 | 2, 4 | |
| 5.1.2 | 4 | |
| 5.1.3 | 4, 9.2 | |
| 5.2 | 9.1, 12.7.1 | |
| 6 | 13.1 | |
| 7 | 5, 7.2 | |
| 8.1 | 13 | |
| 8.2 | 13.6 | |
| 8.3 | 13.6.e) | |



**WARNING:** Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

INTERNATIONAL STANDARD

**ISO 7197**

Third edition
2006-06-01

# Neurosurgical implants — Sterile, single-use hydrocephalus shunts and components

*Implants neurochirurgicaux — Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie*



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# Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 7197 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 3, *Neurosurgical implants*.



This third edition cancels and replaces the second edition (ISO 7197:1997) which has been technically revised.