ILNAS

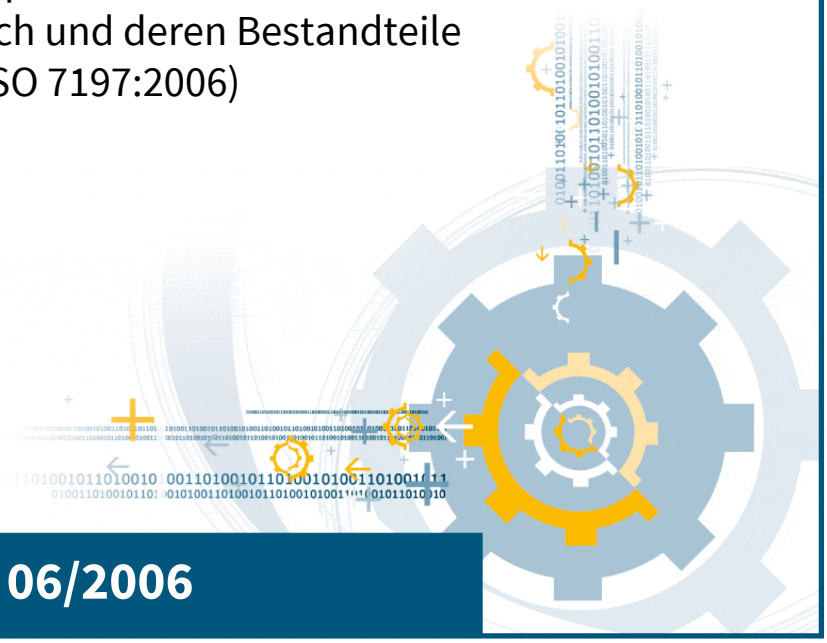
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 7197:2006

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)



06/2006

National Foreword

This European Standard EN ISO 7197:2006 was adopted as Luxembourgish Standard ILNAS-EN ISO 7197:2006.

Every interested party, which is member of an organization based in Luxembourg, can participate for FREE in the development of Luxembourgish (ILNAS), European (CEN, CENELEC) and International (ISO, IEC) standards:

- Participate in the design of standards
- Foresee future developments
- Participate in technical committee meetings

https://portail-qualite.public.lu/fr/normes-normalisation/participer-normalisation.html

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

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

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.