ILNAS

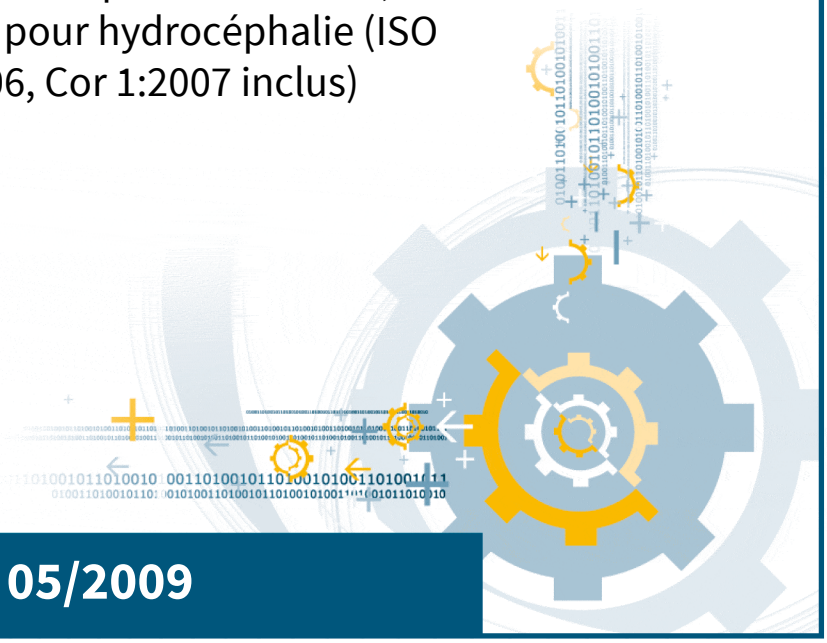
Institut luxembourgeois de la normalisation
de l'accréditation, de la sécurité et qualité
des produits et services

ILNAS-EN ISO 7197:2009

Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007)

Neurochirurgische Implantate - Sterile Hydrozephalus-Shunts zum Einmalgebrauch und deren Bestandteile (ISO 7197:2006, einschließlich Cor 1:2007)

Implants neurochirurgicaux - Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie (ISO 7197:2006, Cor 1:2007 inclus)



05/2009

National Foreword

This European Standard EN ISO 7197:2009 was adopted as Luxembourgish Standard ILNAS-EN ISO 7197:2009.

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

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 7197

May 2009

ICS 11.040.40

Supersedes EN ISO 7197:2006

English Version

Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007)

Implants neurochirurgicaux - Systèmes de dérivation et composants stériles, non réutilisables, pour hydrocéphalie (ISO 7197:2006, Cor 1:2007 inclus)

Neurochirurgische Implantate - Sterile Hydrozephalus-Shunts zum Einmalgebrauch und deren Bestandteile (ISO 7197:2006, einschließlich Cor 1:2007)

This European Standard was approved by CEN on 19 April 2009.

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 CEN Management Centre 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 CEN Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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.

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

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Ref. No. EN ISO 7197:2009: E

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Foreword

The text of ISO 7197:2006, including Cor 1:2007 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 7197:2009 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.

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

This document supersedes EN ISO 7197:2006.

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 EC Directive.

For relationship with EC Directive, 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, 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 the United Kingdom.

Endorsement notice

The text of ISO 7197:2006, including Cor 1:2007 has been approved by CEN as a EN ISO 7197:2009 without any modification.

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
All	1, 2, 3, 4, 5	Part of ER 1 relating to the risk of use error is not covered by current Standard.
4.2	2	
4.3	7.1, 7.2	Part of ER 7.1 relating to biophysical and modelling research is not covered by this European Standard.
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	ER 13.1 is covered via EN ISO 14630.
7	5, 7.2	

8.1	13	The part of ER 13.3.a) relating to the information on the authorized representative is not addressed by this European Standard.
8.2	13.6	The ER 13.3 f is only partly addressed in this European Standard: safety issue of single use. The part of ER 13.6.h) relating to single use is not addressed in this European Standard. ER 13.6 q is not addressed in this European Standard.
8.3	13.6.e)	
	6.a	ER 6.a) is not addressed by this European Standard.

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