SLOVENSKI STANDARD
oSIST prEN ISO 11979-1:2011

01-oktober-2011

Očesni vsadki (implantati) - Intraokularne leče - 1. del: Slovar (ISO/DIS 11979-1:2011)

Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO/DIS 11979-1:2011)

Ophtalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO/DIS 11979-1:2011)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO/DIS 11979-1:2011)

Ta slovenski standard je istoveten z: **prEN ISO 11979-1**

ICS:

01.040.11	Zdravstveno varstvo (Slovarji)	Health care technology (Vocabularies)
11.040.70	Oftalmološka oprema	Ophthalmic equipment

oSIST prEN ISO 11979-1:2011 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN ISO 11979-1

August 2011

ICS 01.040.11; 11.040.70

Will supersede EN ISO 11979-1:2006

English Version

Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO/DIS 11979-1:2011)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO/DIS 11979-1:2011)

Ophtalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO/DIS 11979-1:2011)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 170.

If this draft becomes a European Standard, 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.

This draft European Standard 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, 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.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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: Avenue Marnix 17, B-1000 Brussels

Contents

Page

Foreword.....3

Foreword

This document (prEN ISO 11979-1:2011) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics" in collaboration with Technical Committee CEN/TC 170 “Ophthalmic optics” the secretariat of which is held by DIN.

This document is currently submitted to the parallel Enquiry.

This document will supersede EN ISO 11979-1:2006.

Endorsement notice

The text of ISO/DIS 11979-1:2011 has been approved by CEN as a prEN ISO 11979-1:2011 without any modification.

DRAFT INTERNATIONAL STANDARD ISO/DIS 11979-1

ISO/TC **172**/SC **7** Secretariat: **DIN**

Voting begins on **2011-08-11** Voting terminates on **2012-01-11**

INTERNATIONAL ORGANIZATION FOR STANDARDIZATION • МЕЖДУНАРОДНАЯ ОРГАНИЗАЦИЯ ПО СТАНДАРТИЗАЦИИ • ORGANISATION INTERNATIONALE DE NORMALISATION

Ophthalmic implants — Intraocular lenses —

Part 1: **Vocabulary**

Implants ophtalmiques — Lentilles intraoculaires —

Partie 1: Vocabulaire

[Revision of second edition (ISO 11979-1:2006)]

ICS 01.040.11; 11.040.70

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO-lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five-month enquiry.

Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month approval vote in ISO and formal vote in CEN.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

Contents

Page

Foreword ..... **iv**
Introduction ..... **v**
1 Scope **1**
2 General terms and definitions **1**

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 11979-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition which has been technically revised.

ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

— *Part 1: Vocabulary*

— *Part 2: Optical properties and test methods*

— *Part 3: Mechanical properties and test methods*

— *Part 4: Labelling and information*

— *Part 5: Biocompatibility*

— *Part 6: Shelf-life and transport stability*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

