SLOVENSKI STANDARD
SIST EN ISO 11979-1:2000

01-julij-2000

Oļ esni vsadki (implantati) - Intraokularne leļ e - 1. del: Slovar (ISO 11979-1:1999)

Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:1999)

Ophtalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO 11979-1:1999)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO 11979-1:1999)

Ta slovenski standard je istoveten z: **EN ISO 11979-1:1999**

ICS:

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

SIST EN ISO 11979-1:2000 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-1

December 1999

ICS 01.040.11; 11.040.70

English version

Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:1999)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO 11979-1:1999)

Ophthalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO 11979-1:1999)

This European Standard was approved by CEN on 19 November 1999.

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.

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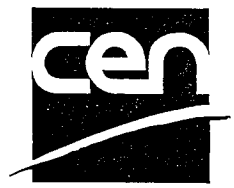

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 11979-1:1999 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics", 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 June 2000, and conflicting national standards shall be withdrawn at the latest by June 2000.

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

NOTE FROM CEN/CS: The foreword is susceptible to be amended on reception of the German language version. The confirmed or amended foreword, and when appropriate, the normative annex ZA for the references to international publications with their relevant European publications will be circulated with the German version.

Endorsement notice

The text of the International Standard ISO 11979-1:1999 was approved by CEN as a European Standard without any modification.

INTERNATIONAL STANDARD

ISO 11979-1

First edition
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Ophthalmic implants — Intraocular lenses —

Part 1: Vocabulary

Implants ophtalmiques — Lentilles intraoculaires — Partie 1: Vocabulaire

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Contents

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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 3.

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.

International Standard ISO 11979-1 was prepared by ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

ISO 11979 consists of several 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*

Introduction

This part of ISO 11979 contains definitions of terms related to intraocular lenses and methods to evaluate them.

In addition to general terms, terms have been grouped in clauses corresponding to the various parts of ISO 11979. The terms are presented alphabetically in each clause.

NOTE It always was and still is the intention of the Technical Committees ISO/TC 172/SC 7 and CEN/TC 170 to prepare identical ISO and CEN (European Committee for Standardization) standards on intraocular lenses. However, during the preparation of part 7 of this series, problems were encountered with normative references to the existing ISO 14155 and EN 540 horizontal standards on clinical investigation of medical devices, which are similar but not identical.

ISO and CEN principles concerning normative references made it impossible to continue the preparation of identical International and European Standards on the clinical investigation of intraocular lenses. As a result, two different standards series have had to be prepared. For this part of ISO 11979, identical versions exist for ISO and CEN (ISO 11979-1 and EN ISO 11979-1). For those parts where no identical versions exist, it is the intention of ISO/TC 172/SC 7 and CEN/TC 170 to revise these standards with the goal to end up with identical ones as soon as identical ISO and CEN horizontal standards on clinical investigations become available.

Ophthalmic implants — Intraocular lenses —

Part 1:
Vocabulary

1 Scope

This part of ISO 11979 defines terms applicable to intraocular lenses and the methods used to evaluate them.

2 General terms and definitions

2.1
anterior chamber (intraocular) lens
intraocular lens designed to be placed entirely in the anterior chamber of the eye

2.2
body
central part of an intraocular lens incorporating the optic

See Figure 1.

2.3
clear optic
diameter of the circle, concentric with the optical axis of an intraocular lens, containing only features of the intraocular lens belonging to the optical design

See Figure 1.

2.4
haptic
non-optical, generally peripheral, component(s) of an intraocular lens intended to keep it in place in the eye

2.5
in situ
in equilibrium with aqueous humour at 35 °C

NOTE 1 The refractive index of aqueous humour is taken to be 1,336 at 546,07 nm.

NOTE 2 For practical testing purposes, physiological saline may in many cases be used as a substitute for aqueous humour.

NOTE 3 Actual testing may be carried out at other conditions if, by validated correction procedures, values can be shown to apply under *in situ* conditions.

2.6
intraocular lens
IOL
ophthalmic lens intended for implantation inside the eye

2.7
loop
peripheral extension on the body, serving to position the lens in the eye

NOTE Loops are parts of the haptic (see 2.4), or may be the haptic.