Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information

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EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN ISO 11979-4:2000 sisaldab Euroopa standardi EN ISO 11979-4:2000 ingliskeelset teksti. Käesolev dokument on jõustatud 15.11.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN ISO 11979-4:2000 consists of the English text of the European standard EN ISO 11979-4:2000. This document is endorsed on 15.11.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This part of EN ISO 11979 specifies the labelling requirements for intraocular lenses (IOLs) and the information to be provided within or on the packaging.	**Scope:** This part of EN ISO 11979 specifies the labelling requirements for intraocular lenses (IOLs) and the information to be provided within or on the packaging.

ICS 11.040.70

Võtmesõnad: intraocular lenses, labelling, lenses, optical equipment, optics, surgical implants, technical data sheets

EUROPEAN STANDARD
NORME EUROPÉENNE
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EN ISO 11979-4

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English version

Ophthalmic implants – Intraocular lenses

Part 4: Labelling and information
(ISO 11979-4 : 2000)

Implants ophtalmiques – Lentilles intraoculaires – Partie 4: Etiquetage et informations (ISO 11979-4 : 2000)

Ophthalmische Implantate – Intraokularlinsen – Teil 4: Etikettierung und Information (ISO 11979-4 : 2000)

This European Standard was approved by CEN on 2000-06-15.

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.

The European Standards exist 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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

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

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Foreword

International Standard

ISO 11979-4 : 2000 Ophthalmic implants – Intraocular lenses – Part 4: Labelling and information,

which was prepared by ISO/TC 172 'Optics and optical instruments' of the International Organization for Standardization, has been adopted by Technical Committee CEN/TC 170 'Ophthalmic optics', the Secretariat of which is held by DIN, as a European Standard.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, and conflicting national standards withdrawn, by December 2000 at the latest.

In accordance with the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard:

Austria, Belgium, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11979-4 : 2000 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to international publications are listed in Annex ZA (normative). A-deviations are given in Annex ZB (informative).

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Introduction

This part of ISO 11979 contains requirements and guidance for the labelling of intraocular lenses and the information supplied with them.

Labelling requirements for medical devices in general are given in EN 1041. However, in order to provide correct and necessary information to the ophthalmic surgeon, some additional information is required for intraocular lenses. This information concerns technical and optical data as well as information about the materials used.

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 11979-4 and EN ISO 11979-4). 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.

1 Scope

This part of ISO 11979 specifies the labelling requirements for intraocular lenses (IOLs) and the information to be provided within or on the packaging.

NOTE This part of ISO 11979 attempts to harmonize the recognized labelling requirements for IOLs throughout the world. However, there may be additional national requirements.

2 Normative reference

The following normative document contains provisions which, through reference in this text, constitute provisions of this part of ISO 11979. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 11979 are encouraged to investigate the possibility of applying the most recent edition of the normative document indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 11979-1:1999, *Ophthalmic implants — Intraocular lenses — Part 1: Vocabulary*.

3 Terms and definitions

For the purposes of this part of ISO 11979, the terms and definitions given in ISO 11979-1 apply.

NOTE Some terms and definitions of ISO 11979-1 relevant to this part of ISO 11979 are reproduced for information in annex A.

4 Labelling

Table 1 lists minimal information that shall be included in the labelling of intraocular lenses and indicates where on the packaging it shall be given. Table 2 lists additional information that shall be given if applicable.