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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11979-4:2009 sisaldab Euroopa standardi EN ISO 11979-4:2008 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11979-4:2009 consists of the English text of the European standard EN ISO 11979-4:2008.
Standard on kinnitatud Eesti Standardikeskuse 29.01.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 29.01.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.12.2008.	Date of Availability of the European standard text 01.12.2008.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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

EUROPEAN STANDARD

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English Version

Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO 11979-4:2008)

Implants ophtalmiques - Lentilles intraoculaires - Partie 4: Étiquetage et informations (ISO 11979-4:2008)

Ophthalmische Implantate - Intraokularlinsen - Teil 4: Etikettierung und Information (ISO 11979-4:2008)

This European Standard was approved by CEN on 29 November 2008.

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Foreword

This document (EN ISO 11979-4:2008) 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of an identical text or by endorsement, at the latest by June 2009, and conflicting national standards shall be withdrawn at the latest by June 2009.

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Endorsement notice

The text of ISO 11979-4:2008 has been approved by CEN as a EN ISO 11979-4:2008 without any modification.

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 ensure 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 materials used.