SLOVENSKI STANDARD
SIST EN ISO 11979-6:2015

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Nadomešča:
SIST EN ISO 11979-6:2008

Očesni vsadki (implantati) - Intraokularne leče - 6. del: Rok uporabnosti in obstojnost pri prevozu (ISO 11979-6:2014)

Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability (ISO 11979-6:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 6: Haltbarkeits- und Transportprüfungen (ISO 11979-6:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 6: Durée de conservation et stabilité pendant le transport (ISO 11979-6:2014)

Ta slovenski standard je istoveten z: **EN ISO 11979-6:2014**

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11.040.70	Oftalmološka oprema	Ophthalmic equipment

SIST EN ISO 11979-6:2015 **en**

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EUROPÄISCHE NORM

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Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability testing (ISO 11979-6:2014)

Implants ophtalmiques - Lentilles intraoculaires - Partie 6: Durée de conservation et stabilité pendant le transport (ISO 11979-6:2014)

Ophthalmische Implantate - Intraokularlinsen - Teil 6: Haltbarkeits- und Transportprüfungen (ISO 11979-6:2014)

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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 11979-6:2014) 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 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of an identical text or by endorsement, at the latest by April 2015, and conflicting national standards shall be withdrawn at the latest by April 2015.

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 11979-6:2007.

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Endorsement notice

The text of ISO 11979-6:2014 has been approved by CEN as EN ISO 11979-6:2014 without any modification.

INTERNATIONAL STANDARD

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Third edition
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Ophthalmic implants — Intraocular lenses —

Part 6: Shelf-life and transport stability testing

Implants ophtalmiques — Lentilles intraoculaires —

Partie 6: Durée de conservation et stabilité pendant le transport

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-6:2007), 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 testing*

— *Part 7: Clinical investigations*

— *Part 8: Fundamental requirements*

— *Part 9: Multifocal intraocular lenses*

— *Part 10: Phakic intraocular lenses*

Introduction

The purpose of a stability study is to ascertain that the properties of a product, in this case an intraocular lens (IOL), remain within specified limits for a sufficiently long period of time under the influence of a variety of environmental conditions.

The storage stability of the intraocular lens material is an important factor in the overall investigation of a new lens material, a new combination of given lens materials, a new packaging material, or a new manufacturing process. To assess this, a study of the ageing of the lenses in their containers is performed.

Changes in the composition and material, material suppliers, manufacturing conditions (including the sterilization process), or the package design or material could affect the shelf-life and could therefore necessitate renewed investigations. The need for studies of product stability, package integrity, and transport stability can be assessed using ISO 14971.

The design of the stability tests should be based on the known properties of the material from which the intraocular lens is made, and the recommendations for use of the intraocular lens. Knowledge of the quantity and identity of extractable substances found after storage or accelerated ageing studies are of importance in evaluating new intraocular lens materials.

On the basis of the information obtained, transport and storage conditions can be recommended that will maintain the quality of the intraocular lens in relation to its safety, efficacy, and acceptability, throughout the proposed shelf-life, i.e. during storage and distribution up until the moment of dispensing. The results obtained are also used to determine the expiration date.

In practical terms, it is the stability of the material from which the intraocular lens is made that is being tested, along with the integrity of the packaging that maintains the necessary environment of the intraocular lens.

Stability studies for intraocular lenses are thus material specific, i.e. this type of study need not be performed for more than one intraocular lens model for a given combination of IOL material(s), packaging materials, and manufacturing processes.