Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability

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EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 11979-6:2008 sisaldab Euroopa standardi EN ISO 11979-6:2007 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 11979-6:2008 consists of the English text of the European standard EN ISO 11979-6:2007.
Standard on kinnitatud Eesti Standardikeskuse 28.01.2008 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 28.01.2008 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
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Ophthalmic implants - Intraocular lenses - Part 6: Shelf-life and transport stability (ISO 11979-6:2007)

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Ophthalmische Implantate - Intraokularlinsen - Teil 6: Haltbarkeits- und Transportprüfungen (ISO 11979-6:2007)

This European Standard was approved by CEN on 23 May 2007.

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Foreword

This document (EN ISO 11979-6:2007) 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of an identical text or by endorsement, at the latest by January 2008, and conflicting national standards shall be withdrawn at the latest by January 2008.

This document supersedes EN 13503-6:2002.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, 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.

Endorsement notice

The text of ISO 11979-6:2007 has been approved by CEN as EN ISO 11979-6:2007 without any modifications.

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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.

Stability studies of intraocular lenses allow the determination of the shelf-life and package suitability as well as recommendations for transport and storage conditions.

Ophthalmic implants — Intraocular lenses —

Part 6:
Shelf-life and transport stability

1 Scope

This part of ISO 11979 specifies tests by which the shelf-life of sterile intraocular lenses (IOLs) in their final packaging can be determined. These tests include procedures to establish the stability of IOLs in distribution and storage.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 10993-5*, Biological testing of medical devices — Tests for in vitro cytotoxicity*

ISO 10993-12, *Biological testing of medical devices — Sample preparation and reference materials*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO/TR 22979, *Ophthalmic implants — Intraocular lenses — Guidance on assessment of the need for clinical investigation of intraocular lens design modifications*

3 Terms and definitions

For the purposes of this document, the terms and definitions of ISO 11979-1 apply.

4 Requirements

4.1 General

If, following a risk analysis in accordance with ISO 14971, it is found that a product stability study, a package integrity study and/or a transport stability study are needed, this part of ISO 11979 shall apply to the planning and conduct of these studies.

A study protocol shall be developed prior to initiation of the study.