



SLOVENSKI STANDARD

oSIST prEN ISO 11979-4:2025

01-maj-2025

Nadomešča:

SIST EN ISO 11979-4:2009/A1:2013

Očesni vsadki (implantati) - Intraokularne leče - 4. del: Označevanje in informacije (ISO/DIS 11979-4:2025)

Ophthalmic implants - Intraocular lenses - Part 4: Labelling and information (ISO/DIS 11979-4:2025)

Ophthalmische Implantate - Intraokularlinsen - Teil 4: Etikettierung und Information
(ISO/DIS 11979-4:2025)

Implants ophtalmiques - Lentilles intraoculaires - Partie 4: Étiquetage et informations
(ISO/DIS 11979-4:2025)

Ta slovenski standard je istoveten z: prEN ISO 11979-4

<https://standards.iteh.ai/catalog/standards/sist/435c3abc-7dc9-4b9f-901f-4e9cd735cec9/osist-pren-iso-11979-4-2025>

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment
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en,fr,de



DRAFT International Standard

ISO/DIS 11979-4.2

Ophthalmic implants — Intraocular lenses —

Part 4: Labelling and information

Implants ophtalmiques — Lentilles intraoculaires —

Partie 4: Étiquetage et informations

ICS: 11.040.70

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Foreword

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This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This third edition cancels and replaces the second edition (ISO 11979-4:2008), which has been technically revised.

The main changes are as follows:

- normative references have been updated and retired standards have been removed or replaced;
- [Table 1](#) has been updated with additional information to be included in the packaging; e.g. expiration date on primary package
- instructions for use has been extended with the minimum requirements of the device description including the abbreviations for the applicable SVIOL category according to ISO 11979-7:2024
- information can be provided electronically if national regulations allow.

A list of all parts in the ISO 11979 series can be found on the ISO website.