SLOVENSKI STANDARD
oSIST prEN ISO 11979-4:2025

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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**

ICS:

11.040.70	Oftalmološka oprema	Ophthalmic equipment

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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

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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.