

SLOVENSKI STANDARD oSIST prEN ISO 18369-1:2025

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Očesna optika - Kontaktne leče - 1. del: Slovar, sistem razvrstitve in priporočila za označevanje specifikacij (ISO/DIS 18369-1:2025)

Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications (ISO/DIS 18369-1:2025)

Augenoptik - Kontaktlinsen - Teil 1: Begriffe, Einteilung von Kontaktlinsenmaterialien und Empfehlungen für die Schreibweise von Kontaktlinsenspezifikationen (ISO/DIS 18369-1:2025)

(https://standards.iteh.ai)

Optique ophtalmique - Lentilles de contact - Partie 1: Vocabulaire, système de classification et recommandations pour l'étiquetage des spécifications (ISO/DIS 18369-1:2025)

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ICS:

01.040.11 Zdravstveno varstvo Health care technology

(Slovarji) (Vocabularies)

11.040.70 Oftalmološka oprema Ophthalmic equipment

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DRAFTInternational Standard

ISO/DIS 18369-1

Ophthalmic optics — Contact lenses —

Part 1:

Vocabulary, classification system and recommendations for labelling specifications

Optique ophtalmique — Lentilles de contact —

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Foreword

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

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 18369-1:2017), which has been technically revised.

The main changes are as follows:

- Editorial update of the whole document; 76466-5880-4973
- Add six new definitions related to scleral contact lenses and extend <u>Annex A</u> (informative) to include representative examples of the specifications for lathe-cut scleral contact lenses of varying complexity using the standard notation of this document.

A list of all parts in the ISO 18369 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

The ISO 18369 series applies to contact lenses, which are devices worn over the front surface of the eye in contact with the preocular tear film. This document covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape. Soft contact lenses are easily deformable and require support for proper shape.

<u>Clause 3</u> contains the terms and definitions primarily used in the contact lens field. A list of terms having special symbols is given in <u>Table 1</u>.

The list of terms and definitions does not include all ISO terms, definitions, and symbols used in the contact lens field. It is intended to be a convenient reference source from which the contents have been compiled from the text of this and other ISO standards applicable to the manufacture, evaluation, measurement, labelling and marketing of contact lenses and contact lens care products. An alphabetical index was added for rapid finding of terms.

Words are grouped under several topics by reference number according to the general category into which each word logically fits. The preferred form of each term is listed on the first line after its reference number. Other admitted forms have been placed on subsequent lines after the preferred form. All admitted terms are given in bold-faced type. A few obsolete and superseded terms are listed for historical reference and convenience and to aid comprehension but are indicated as deprecated and are no longer to be used. Obsolete and superseded terms are not in bold-faced type so that they may be clearly identified as terms used historically.

Contact lenses are primarily used for the correction of refractive errors but they can also be used for therapeutic purposes and cosmetic reasons. The materials used are divided into two main categories, rigid and soft. The former is composed mainly of corneal lenses and to a lesser extent, scleral lenses. Both types can be made from gas-permeable materials or non-gas permeable materials. Soft lenses are manufactured primarily from hydrogel materials. A small number of lenses incorporate both a rigid material and a soft material.

In terms of vision correction, contact lenses can be made as single-vision, bifocal, multifocal or progressive lenses. Surface designs can be spherical, aspheric, toric or "complex".

Wearing modality can be daily wear, flexible wear, or extended wear. Typical replacement schedules for soft lenses are daily, two weekly, or monthly. Rigid lenses and some soft lenses are replaced less often, for 2025 example, once a year.