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Očesna optika - Kontaktne leče - 1. del: Slovar, sistem razvrstitve in priporočila za označevanje specifikacij (ISO 18369-1:2017)

Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications (ISO 18369-1:2017)

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Augenoptik - Kontaktlinsen - Teil 1: Begriffe, Einteilung von Kontaktlinsenmaterialien und Empfehlungen für die Schreibweise von Kontaktlinsenspezifikationen (ISO 18369-1:2017)

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Optique ophtalmique - Lentilles de contact - Partie 1: Vocabulaire, système de classification et recommandations pour l'étiquetage des spécifications (ISO 18369-1:2017)

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 18369-1

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English Version

**Ophthalmic optics - Contact lenses - Part 1: Vocabulary,
classification system and recommendations for labelling
specifications (ISO 18369-1:2017)**

Optique ophtalmique - Lentilles de contact - Partie 1:
Vocabulaire, système de classification et
recommandations pour l'étiquetage des spécifications
(ISO 18369-1:2017)

Augenoptik - Kontaktlinsen - Teil 1: Begriffe, Einteilung
von Kontaktlinsenmaterialien und Empfehlungen für
die Schreibweise von Kontaktlinsenspezifikationen
(ISO 18369-1:2017)

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CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 18369-1:2017) 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of an identical text or by endorsement, at the latest by March 2018, and conflicting national standards shall be withdrawn at the latest by March 2018.

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INTERNATIONAL
STANDARD

ISO
18369-1

Second edition
2017-08

**Ophthalmic optics — Contact lenses —
Part 1:
Vocabulary, classification system
and recommendations for labelling
specifications**

iTeh STANDARD PREVIEW
Optique ophtalmique — Lentilles de contact —

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*Partie 1: Vocabulaire, système de classification et recommandations
pour l'étiquetage des spécifications*

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html. (standards.iteh.ai)

This document was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*. [SIST EN ISO 18369-1:2017](https://standards.iteh.ai/catalog/standards/sist/64e535af-d1e1-4adc-bbe7-12326191f18369-1:2017)

This second edition cancels and replaces the first edition (ISO 18369-1:2006), which has been technically revised. It also incorporates the Amendment ISO 18369-1:2006/Amd 1:2009.

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

Introduction

The ISO 18369 series applies to contact lenses, which are devices worn over the front surface of the eye in contact with the precorneal 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.

[Clause 3](#) contains the terms and definitions primarily used in the contact lens field. A list of terms having special symbols is given in [Table 1](#).

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 example, once a year.

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Ophthalmic optics — Contact lenses —

Part 1:

Vocabulary, classification system and recommendations for labelling specifications

1 Scope

This document identifies and defines the terms applicable to the physical, chemical and optical properties of contact lenses, their manufacture and uses. It provides a vocabulary of terms and, when appropriate, the international symbol and abbreviation associated with a specific term. This document also defines the terms relating to contact lens care products. It also incorporates the classifications of contact lens materials and gives recommendations for the labelling of the specifications of contact lenses.

2 Normative references

There are no normative references in this document.

3 Terms, definitions and symbols

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1 Terms and definitions

3.1.1 Basic terms

3.1.1.1

contact lens

ophthalmic lens designed to be worn on the front surface of the eye

Note 1 to entry: This term includes contact lenses of plano power.

3.1.1.2

corneal contact lens

intralimbal contact lens

contact lens (3.1.1.1) having a total diameter less than the visible iris diameter and designed to be worn in its entirety on the cornea

3.1.1.3

scleral contact lens

contact lens (3.1.1.1) whose *scleral zone* (3.1.5.12) is supported on the bulbar conjunctiva and whose *optic zone* (3.1.2.1.17) vaults over the cornea

Note 1 to entry: Note1 to entry: In some cases, the *back optic zone* (3.1.2.2.1) will have minimal corneal touch.

Note 2 to entry: Terms such as mini-scleral, semi-scleral and corneo-scleral can be found in the contact lens literature to describe lenses of different parameters.

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Note 3 to entry: See [3.1.5](#) for specific terms concerning scleral contact lenses.

3.1.1.4

lenticular contact lens

contact lens ([3.1.1.1](#)) having a front *optic zone* ([3.1.2.1.17](#)) made smaller than the total diameter

Note 1 to entry: This construction is conventionally used to reduce the *centre thickness* ([3.1.2.4.1](#)) of a *positive power contact lens* ([3.1.2.1.13](#)) or reduce the *edge* ([3.1.2.1.34](#)) thickness of a *negative power contact lens* ([3.1.2.1.14](#)).

3.1.1.5

contact shell

contact lens ([3.1.1.1](#)) not designed to correct vision

3.1.1.6

scleral shell

rigid contact shell ([3.1.1.5](#)) with a *scleral zone* ([3.1.5.12](#))

Note 1 to entry: See [3.1.5](#) for specific terms concerning scleral shells.

3.1.1.7

rigid contact lens

contact lens ([3.1.1.1](#)) which, in its final state and under normal conditions, retains its form without support and has a *water content* ([3.1.6.11](#)) less than 10 %

Note 1 to entry: Rigid lenses are made of non-hydrogel rigid materials which can flex slightly but do not substantially conform to the shape of the cornea when on the eye.

3.1.1.8

rigid gas-permeable contact lens**RGP contact lens**

DEPRECATED: hard gas-permeable contact lens
contact lens ([3.1.1.1](#)) manufactured from a rigid material containing one or more gas-permeable polymers in sufficient concentrations to facilitate transport of oxygen through the lens and having a *Dk* equal to or greater than 10 *Dk* units

Note 1 to entry: For an explanation of the meaning of *Dk* and *Dk* units, see [3.1.6.8](#).

3.1.1.9

soft contact lens

contact lens ([3.1.1.1](#)) made of a hydrogel material or non-hydrogel material which, in its hydrated final state and under normal conditions, contains a known *water content* ([3.1.6.11](#)), is easily deformable and may not retain its form without support

3.1.1.10

hydrogel contact lens

DEPRECATED: hydrophilic contact lens

contact lens ([3.1.1.1](#)) made of water-absorbing material having equilibrium *water content* ([3.1.6.11](#)) greater than or equal to 10 % in standard saline solution as specified in ISO 18369-3 at 20 °C

3.1.1.11

composite contact lens

contact lens ([3.1.1.1](#)) composed of two or more different materials

EXAMPLE Laminated lens, fused segment lens, lens with a rigid centre and a flexible periphery.

3.1.1.12

surface-treated contact lens

contact lens ([3.1.1.1](#)) whose surfaces have been modified to make the surface characteristics different to those of the bulk material

3.1.1.13**bifocal contact lens**

multifocal contact lens (3.1.1.14) having two *optic zones* (3.1.2.1.17), usually for distance and near-vision correction

Note 1 to entry: See 3.1.4 for specific terms concerning bifocal contact lenses.

3.1.1.14**multifocal contact lens**

contact lens (3.1.1.1) designed to provide two or more zones of different corrective powers

Note 1 to entry: See 3.1.4 for specific terms concerning multifocal contact lenses.

3.1.1.15**progressive power contact lens****varifocal power contact lens**

contact lens (3.1.1.1) designed to provide correction for more than one viewing range in which the power changes continuously, rather than discretely, over a part or the whole of the lens

Note 1 to entry: See 3.1.4 for specific terms concerning progressive power contact lenses.

3.1.1.16**spherical aberration**

attribute of an optical system due to variation in the focusing between peripheral and paraxial rays

3.1.1.17**contact lens accessory**

article intended specifically by its manufacturer to be used with a *contact lens* (3.1.1.1) to enable the lens to be used in accordance with its *intended purpose* (3.1.9.1)

Note 1 to entry: This term includes all devices to clean, handle, store or manipulate lenses for intended use.

Note 2 to entry: This definition does not include the *primary packaging* (3.1.9.7), e.g. vials, *blister packs* (3.1.9.5) or mailers, intended by the manufacturer to be used only for shipment of the contact lenses.

3.1.1.18**contact lens care product**

contact lens accessory (3.1.1.17) intended for use in maintaining the safety and *performance* (3.1.9.2) of a *contact lens* (3.1.1.1) after opening and removal of the lens from its *primary container* (3.1.9.7)

Note 1 to entry: See 3.1.9 and 3.1.11 for specific terms concerning contact lens care products and the hygienic management of contact lenses.

3.1.1.19**suction cup**

handheld device designed with a small concave flexible tip intended to aid the insertion of a *contact lens* (3.1.1.1) onto or removal from the eye by means of suction

Note 1 to entry: A suction cup is designed primarily for use with rigid *corneal contact lenses* (3.1.1.2) and *scleral contact lenses* (3.1.1.3).

3.1.1.20**contact lens container****storage container****contact lens case****storage case**

device in which *contact lenses* (3.1.1.1) are stored either dry (rigid corneal and scleral lenses), or in a suitable solution (rigid gas permeable lenses, hydrogel and other soft lenses), by the user after removal from the *primary container* (3.1.9.7) or the eye