



SLOVENSKI STANDARD SIST EN ISO 18369-1:2006

01-december-2006

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SIST EN ISO 11539:2001

SIST EN ISO 8320-1:2003

SIST EN ISO 8320-2:2002

SIST EN ISO 8321-1:2002

SIST EN ISO 8321-2:2000

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iTeh STANDARD PREVIEW

Ophthalmic optics - Contact lenses - Part 1: Vocabulary, classification system and recommendations for labelling specifications (ISO 18369-1:2006)

[SIST EN ISO 18369-1:2006](#)

Augenoptik - Kontaktlinsen - Teil 1: Begriffe, Einteilung von Kontaktlinsenmaterialien und Empfehlungen für die Schreibweise von Kontaktlinsenspezifikationen (ISO 18369-1:2006)

Optique ophtalmique - Lentilles de contact - Partie 1: Vocabulaire, systeme de classification et recommandations pour l'étiquetage des spécifications (ISO 18369-1:2006)

Ta slovenski standard je istoveten z: EN ISO 18369-1:2006

ICS:

01.040.11	Zdravstveno varstvo (Slovarji)	Health care technology (Vocabularies)
11.040.70	Oftalmološka oprema	Ophthalmic equipment

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en,fr,de

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ICS 01.040.11; 11.040.70

Supersedes EN ISO 8320-1:2003, EN ISO 8320-2:2001
and EN ISO 11539:1999,
and partly supersedes EN ISO 8321-1:2002 and
EN ISO 8321-2:2000

English Version

Ophthalmic optics - Contact lenses - Part 1: Vocabulary,
classification system and recommendations for labelling
specifications (ISO 18369-1:2006)

Optique ophtalmique - Lentilles de contact - Partie 1:
Vocabulaire, système de classification et recommandations
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Augenoptik - Kontaktlinsen - Teil 1: Begriffe, Einteilung von
Kontaktlinsenmaterialien und Empfehlungen für die
Schreibweise von Kontaktlinsenspezifikationen (ISO 18369-
1:2006)

This European Standard was approved by CEN on 19 May 2006.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, 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.



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EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This document (EN ISO 18369-1:2006) 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 February 2007, and conflicting national standards shall be withdrawn at the latest by February 2007.

This document supersedes EN ISO 8320-1:2003, EN ISO 8320-2:2001 and EN ISO 11539:1999 and partly supersedes EN ISO 8321-1:2002 and EN ISO 8321-2:2000.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, 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 18369-1:2006 has been approved by CEN as EN ISO 18369-1:2006 without any modifications.

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NOTE: A-Deviations are given in Annex ZA (informative)

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ANNEX ZA (informative)
A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN/CENELEC member.

This European Standard does not fall under any Directive of the EC. In the relevant CEN/CENELEC countries these A-deviations are valid instead of the provisions of the European Standard until they have been removed.

The legislative situation in Germany requires the unit "dioptré" be designated by the symbol "dpt" instead of "D".

This is to avoid conflict with the rules of ISO 1000 being the basic International Standard on symbols and units and with the respective basic resolution of the CGPM (International Conference on Weights and Measures).

Identification of the regulation:

Gesetz über die Einheiten im Messwesen vom 02.07.1969 in der Fassung der Bekanntmachung vom 22.04.1985; and

Ausführungsverordnung zum Gesetz über Einheiten im Messwesen (Einheitenverordnung - EinhV) vom 13.12.1985, § 1 und Anlage 1, Nr. 9.

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

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 18369-1 was prepared by Technical Committee ISO/TC 172, *Optics and photonics*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

This first edition cancels and replaces ISO 8320-1:2003, ISO 8320-2:2001 and ISO 11539:1999, which have been technically revised. Furthermore, together with ISO 18369-2, it cancels and replaces ISO 8321-1:2002 and ISO 8321-2:2000, which have been technically revised.

ISO 18369 consists of the following parts, under the general title *Ophthalmic optics — Contact lenses*:

- Part 1: Vocabulary, classification system and recommendations for labelling specifications
- Part 2: Tolerances
- Part 3: Measurement methods
- Part 4: Physicochemical properties of contact lens materials

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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 part of ISO 18369 covers rigid (hard) corneal and scleral contact lenses, as well as soft contact lenses. Rigid lenses maintain their own shape unsupported and are made of transparent optical-grade plastics, such as polymethylmethacrylate (PMMA), cellulose acetate butyrate (CAB), polyacrylate/siloxane copolymers, rigid polysiloxanes (silicone resins), butylstyrenes, fluoropolymers, and fluorosiloxanes, etc. Soft contact lenses are easily deformable and require support for proper shape. A very large subset of soft contact lenses consists of transparent hydrogels containing water in concentrations greater than 10 %. Soft contact lenses can also be made of non-hydrogel materials, e.g. flexible polysiloxanes (silicone elastomers).

The ISO 18369 series is applicable to determining allowable tolerances of parameters and properties important for proper functioning of contact lenses as optical devices. The ISO 18369 series includes tolerances for single vision contact lenses, bifocal lenses, lenses that alter the flux density and/or spectral composition of transmitted visible light (tinted or pigmented contact lenses, such as those with enhancing, handling, and/or opaque tints), and lenses that significantly attenuate ultraviolet radiation (UVR absorbing lenses). The ISO 18369 series covers contact lenses designed with spherical, toric, and aspheric surfaces, and recommended methods for the specification of contact lenses.

The vocabulary portion (2.1) of this part of ISO 18369 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 fitted. 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 as an aid to 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.

Figure 1 gives a schema of the classification and provides examples. It does not take into account all possible characteristics (hence resulting qualifiers) used in contact lens designation. Combinations of more than one qualifier are often used in contact lens designation.

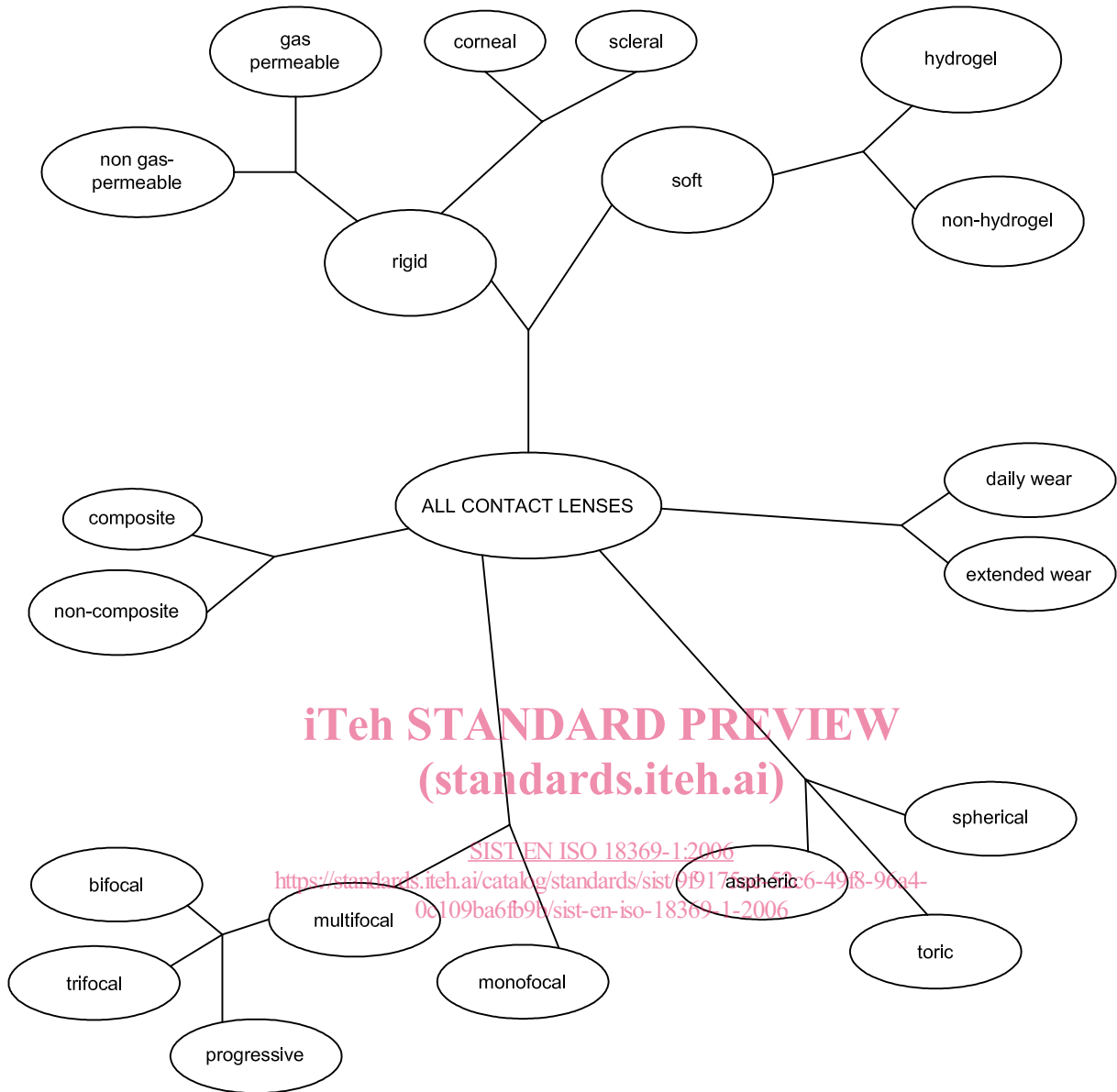


Figure 1 — Classification of contact lenses according to various characteristics leads to various qualifiers used in their designation

Ophthalmic optics — Contact lenses —

Part 1: Vocabulary, classification system and recommendations for labelling specifications

1 Scope

This part of ISO 18369 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 part of ISO 18369 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 Terms, definitions and symbols

2.1 Terms and definitions

2.1.1 Basic terms

2.1.1.1 contact lens

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

NOTE This term includes contact lenses of plano power.

2.1.1.2 corneal contact lens

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

2.1.1.3 scleral contact lens

contact lens designed to be worn in front of the cornea and on the adjacent portion of the surrounding bulbar conjunctiva

NOTE See 2.1.5 for specific terms concerning scleral contact lenses.

2.1.1.4 lenticular contact lens

contact lens having a front optic zone made smaller than the total diameter

NOTE This construction is conventionally used to reduce the centre thickness of a positive power contact lens or reduce the edge thickness of a negative power contact lens.

2.1.1.5 contact shell

contact lens not designed to correct vision

2.1.1.6

scleral shell

rigid contact shell with a scleral zone

NOTE See 2.1.5 for specific terms concerning scleral shells.

2.1.1.7

rigid contact lens

hard contact lens

contact lens which, in its final form and under normal conditions, retains its form without support

2.1.1.8

rigid gas-permeable contact lens

RGP contact lens

hard gas-permeable contact lens (deprecated)

rigid contact lens which contains one or more components in the contact lens polymer in sufficient concentration to permit oxygen transmission through the contact lens

2.1.1.9

soft contact lens

contact lens which requires support to maintain its form

2.1.1.10

hydrogel contact lens

hydrophilic contact lens (deprecated)

contact lens made of water-absorbing material having equilibrium water content greater than or equal to 10 % in standard saline solution at 20 °C

NOTE Standard saline solution is prepared as specified in ISO 18369-3.

2.1.1.11

composite contact lens

contact lens composed of two or more different materials

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

2.1.1.12

surface treated contact lens

contact lens whose surfaces have been modified to make the surface characteristics different to those of the bulk material

2.1.1.13

bifocal contact lens

multifocal contact lens having two optic zones, usually for distance and near-vision correction

NOTE See 2.1.4 for specific terms concerning bifocal contact lenses.

2.1.1.14

multifocal contact lens

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

NOTE See 2.1.4 for specific terms concerning multifocal contact lenses.

2.1.1.15

progressive power contact lens

varifocal power contact lens

contact lens 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 See 2.1.4 for specific terms concerning progressive power contact lenses.

2.1.1.16**contact lens accessory**

article intended specifically by its manufacturer to be used with a contact lens to enable the lens to be used in accordance with its intended purpose

NOTE This term includes all devices recommended for use in the hygienic management of contact lenses, for hydrating contact lenses, or alleviating discomfort of contact lens wear by physical means.

2.1.1.17**contact lens care product**

contact lens accessory intended for use in maintaining the safety and performance of a contact lens after opening and removal of the lens from its primary container

NOTE See 2.1.9 and 2.1.11 for specific terms concerning contact lens care products and the hygienic management of contact lenses.

2.1.1.18**other accessory for contact lenses**

item used for handling contact lenses or as a part of a contact lens care regimen excluding contact lens care products

EXAMPLE Suction cup used to aid in the insertion of a contact lens onto or removal from the surface of the eye.

NOTE This definition does not include the primary packaging (e.g. vials, blister packs or mailers) intended by the manufacturer to be used only for shipment of the contact lenses.

2.1.1.19**suction cup**

hand-held device designed with a small concave flexible tip intended to aid the insertion of a contact lens onto or removal from the eye by means of suction

NOTE A suction cup is designed primarily for use with rigid corneal contact lenses.

2.1.1.20**contact lens container
storage container**

contact lens case

storage case

container in which contact lenses are stored either dry or in a suitable solution by the user after removal from the primary container or the eye

2.1.2 Contact lens parameters and design**2.1.2.1 General terms****2.1.2.1.1****front vertex power**

F_v

reciprocal of the paraxial front vertex focal length

[ISO 13666:1998]

NOTE The front vertex power is expressed in dioptres.

2.1.2.1.2**back vertex power**

F'_v

reciprocal of the paraxial back vertex focal length

[ISO 13666:1998]

NOTE The back vertex power is expressed in dioptres.