

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

Ophthalmic optics - Contact lenses - Part 1:
Vocabulary, classification system and
recommendations for the labelling of specifications

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

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| <p>Käesolev Eesti standard EVS-EN ISO 18369-1:2006 sisaldab Euroopa standardi EN ISO 18369-1:2006 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 27.10.2006 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p> | <p>This Estonian standard EVS-EN ISO 18369-1:2006 consists of the English text of the European standard EN ISO 18369-1:2006.</p> <p>This document is endorsed on 27.10.2006 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p> |
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| <p>Käsitlusala:</p> <p>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 recommendation for the labelling of the specifications of contact lenses.</p> <p>Asendab osaliselt: EN ISO 8321-1:2002 ja EN ISO 8321-2:2000</p> | <p>Scope:</p> <p>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 recommendation for the labelling of the specifications of contact lenses.</p> <p>Asendab osaliselt: EN ISO 8321-1:2002 ja EN ISO 8321-2:2000</p> |
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ICS 01.040.11, 11.040.70

Võtmesõnad: classification, contact lenses, lenses, methodology, ophthalmic equipment, optical equipment, optics

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EN ISO 18369-1

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and EN ISO 11539:1999,
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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
pour l'étiquetage des spécifications (ISO 18369-1:2006)

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.

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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.

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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.

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

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.

Ophthalmic optics — Contact lenses —

Part 1:

**Vocabulary, classification system and
recommendations for labelling
specifications**

Optique ophtalmique — Lentilles de contact —

*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*

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.

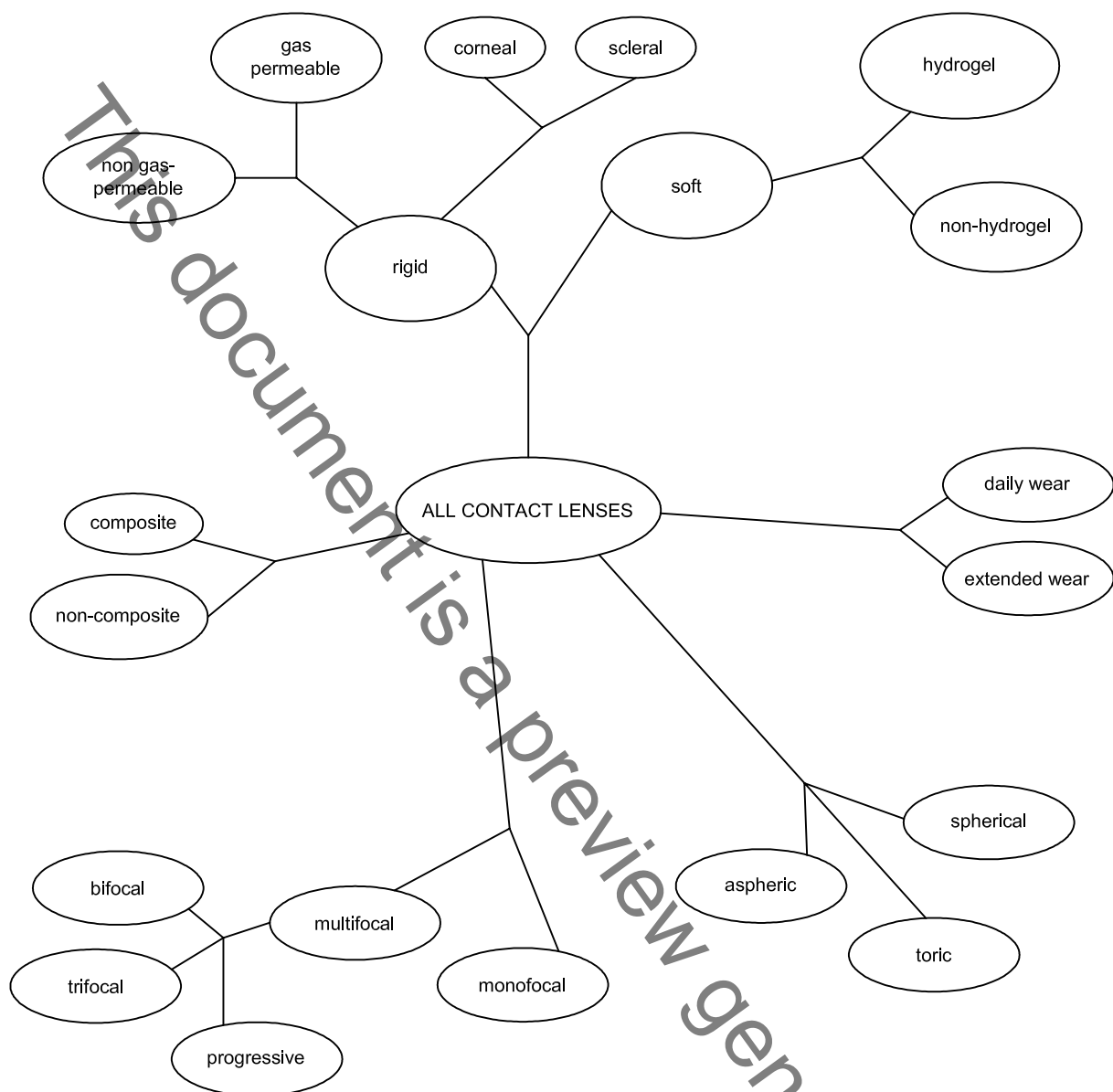


Figure 1 — Classification of contact lenses according to various characteristics leads to various qualifiers used in their designation

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