
C YgbUcdh_U!`?cbhU_hbY`Y Y!`FUnj fy Ub`Y`_cbhU_hb] `Y `]b`a Uhf]Ucj `nU
_cbhU_hbY`Y YfIGC`%)' -.%- -- Ł

Ophthalmic optics - Contact lenses - Classification of contact lenses and contact lens materials (ISO 11539:1999)

Augenoptik - Kontaktlinsen - System zur Einteilung von Kontaktlinsen und Kontaktlinsenmaterialien (ISO 11539:1999)

Optique ophtalmique - Lentilles de contact - Classification des lentilles de contact et de leurs matériaux constructifs (ISO 11539:1999)

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Ta slovenski standard je istoveten z: EN ISO 11539:1999

ICS:

11.040.70 Oftalmološka oprema Ophthalmic equipment

SIST EN ISO 11539:2001 en

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ICS 11.040.70

English version

Ophthalmic optics - Contact lenses - Classification of contact lenses and contact lens materials (ISO 11539:1999)

Optique ophtalmique - Lentilles de contact - Classification des lentilles de contact et de leurs matériaux constructifs (ISO 11539:1999)

Augenoptik - Kontaktlinsen - System zur Einteilung von Kontaktlinsen und Kontaktlinsenmaterialien (ISO 11539:1999)

This European Standard was approved by CEN on 7 July 1999.

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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

Foreword

The text of the International Standard ISO 11539:1999 has been prepared by Technical Committee ISO/TC 172 "Optics and optical instruments" 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 2000, and conflicting national standards shall be withdrawn at the latest by February 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Endorsement notice

The text of the International Standard ISO 11539:1999 was approved by CEN as a European Standard without any modification.

NOTE: Normative references to International Standards are listed in annex ZA (normative).

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AGENCIJA ZA VEŠTAČENJE I
TEHNIČKI VEŠTAČKI CENTAR
REPUBLIKE HRVATSKE
IZ OBLASTI OPTIKE I OPTIČKIH
POMAGALA

IZ OBLASTI OPTIKE I OPTIČKIH
POMAGALA

ANNEX ZA (normative)**Normative references to international publications with their corresponding European publications**

This European Standard incorporates by dated or undated references, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

Publication	Year	Title	EN	Year
ISO 9913-1	1996	Optics and optical instruments - Contact lenses - Part 1: Determination of oxygen permeability and transmissibility with the FATT method	EN ISO 9913-1	1998
ISO 10339	1997	Ophthalmic optics - Contact lenses - Determination of water content of hydrogel lenses	EN ISO 10339	1999

[SIST EN ISO 11539:2001](https://standards.iteh.ai/catalog/standards/sist/5abfce6f-0e46-4fe1-ac28-6fdec58acd7/sist-en-iso-11539-2001)

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INTERNATIONAL
STANDARD

ISO
11539

First edition
1999-08-01

**Ophthalmic optics — Contact lenses —
Classification of contact lenses and contact
lens materials**

*Optique ophtalmique — Lentilles de contact — Classification des lentilles de
contact et de leurs matériaux constitutifs*

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Reference number
ISO 11539:1999(E)

ISO 11539:1999(E)**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 3.

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.

International Standard ISO 11539 was prepared by Technical Committee ISO/TC 172, *Optics and optical instruments*, Subcommittee SC 7, *Ophthalmic optics and instruments*.

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Printed in Switzerland

Ophthalmic optics — Contact lenses — Classification of contact lenses and contact lens materials

1 Scope

This International Standard describes a method for classifying contact lenses and the materials used for their manufacture. It permits the specific and non-proprietary identification, in simplified form, of the major chemical components of the material.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8320-1, *Contact lenses and contact lens care products — Vocabulary — Part 1: Contact lenses.*

[SIST EN ISO 11539:2001](#)

ISO 9913-1, *Optics and optical instruments — Contact lenses — Part 1: Determination of oxygen permeability and transmissibility with the FATT method.*

[6fdec58acd7/sist-en-iso-11539-2001](#)

ISO 9913-2, *Optics and optical instruments — Contact lenses — Part 2: Determination of oxygen permeability and transmissibility by the coulometric method.*

ISO 10339, *Ophthalmic optics — Contact lenses — Determination of water content of hydrogel lenses.*

3 Terms and definitions

For the purposes of this International Standard, the terms and definitions given in ISO 8320-1 apply.

4 Method of classification

4.1 General

The specific classification of a contact lens or contact lens material is given as a **six-part code** as follows:

(prefix) (stem) (series suffix) (group suffix) (Dk range) (modification code)

For hydrogel contact lens materials, the classification denotes whether the material is ionic and the range in which the water content of the material lies. For non-hydrogel contact lens materials, the classification indicates the presence/absence of silicon/fluorine and the oxygen permeability grouping.

For both types of material, the presence or absence of surface modifications is noted (see 4.7).