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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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Foreword

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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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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*.

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

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).

4.2 Prefix

The prefix is a term assigned to a material to designate a specific chemical formulation. Use of this prefix, which is administered by the United States Adopted Names (USAN) Council¹⁾, is optional for all countries other than the United States of America.

4.3 Stem

Two types of stem are used. The **filcon** stem is affixed to the prefix and is applied for materials which contain ≥ 10 % water by mass (hydrogel materials). The **focon** stem is affixed to the prefix and is applied for materials which contain < 10 % water by mass (non-hydrogel materials).

4.4 Series suffix

The series suffix is also administered by the USAN Council, and is used in cases in which the original ratio of monomers of an existing contact lens polymeric material is changed to make a new contact lens polymeric material. In this case, the capital letter "A" is added after the stem designation. Subsequent changes in monomer ratio are designated by the next letter of the alphabet. These letters are used to differentiate copolymers of unchanged monomer units but with different ratios. The series suffix may be omitted in cases where there is only one unique monomer ratio.

4.5 Group suffix

4.5.1 For **hydrogel** (filcon) materials, the group suffix, represented by a Roman numeral, indicates the range of water content in accordance with ISO 10339 and the ionic content:

I low water content, non-ionic: Materials which contain less than 50 % water and which contain 1 % or less (expressed as mole fraction) of monomers that are ionic at pH 7,2.

II medium and high water content, non-ionic: Materials which contain 50 % water or more, and which contain 1 % or less (expressed as mole fraction) monomers which are ionic at pH 7,2.

III low water content, ionic: Materials which contain less than 50 % water and which contain greater than 1 % (expressed as mole fraction) monomers which are ionic at pH 7,2.

IV medium and high water content, ionic: Materials which contain 50 % water or more, and which contain greater than 1 % (expressed as mole fraction) monomers which are ionic at pH 7,2.

NOTE Low water content is defined as less than 50 % water; medium water content as from 50 % to 65 % water, inclusive; and high water content as greater than 65 % water. Hence, group suffixes II and IV include all materials having water contents of 50 % or greater.

4.5.2 For **non-hydrogel** (focon) materials, the group suffix, represented by a Roman numeral, indicates the presence or absence of silicon and/or fluorine:

I Materials which do not contain either silicon or fluorine

II Materials which contain silicon but not fluorine

III Materials which contain both silicon and fluorine

IV Materials which contain fluorine but not silicon

NOTE Polymer formulations may also contain initiators, catalysts, fillers and wetting agents which may be present in the final material. For clarity and simplicity, these additives have been omitted from the stated composition.

¹⁾ United States Adopted Names Council, c/o American Medical Association, P.O. Box 10970, Chicago, IL, USA, 60610.

4.6 Oxygen permeability range (Dk range)

This part of the classification code is presented as a numerical designation which categorizes the oxygen permeability, in Dk units, of the material in ranges which are considered to be of significance in contact lens wear. For contact lenses and contact lens materials, the oxygen permeability is measured in accordance with ISO 9913-1 or ISO 9913-2. The permeability is then denoted in the classification code by the appropriate number corresponding to one of the following categories:

0	< 1 Dk unit	4	61 to 100 Dk units
1	1 to 15 Dk units	5	101 to 150 Dk units
2	16 to 30 Dk units	6	151 to 200 Dk units
3	31 to 60 Dk units	7	etc., increasing in increments of 50 Dk units

4.7 Modification code

The modification code is presented as a lower case “m”, and denotes that the contact lens has a modified surface which has different characteristics from that of the bulk material. Examples of surface modification processes to which the contact lens may have been subjected include: plasma treatment, acid/base hydrolysis, incorporation of a material which migrates to the surface, etc. Certain types of tinted contact lenses may also be considered surface-modified. In the case of an unmodified surface, this suffix is omitted.

4.8 Examples of classification by code

4.8.1 Example of hydrogel material

A hydrogel material whose formulation has the USAN code “Cromo”, of monomer ratio modification “A”, containing 78 % water, 0,6 % mole fraction ionic monomers and exhibiting an oxygen permeability of 45 Dk units is classified by the following code:

Cromofilcon A II 3

4.8.2 Example of non-hydrogel material

A non-hydrogel material whose formulation has the USAN code “Fluorsil”, containing both silicon and fluorine, exhibiting an oxygen permeability of 132 Dk units and subjected to plasma treatment is classified by the following code:

Fluorsilfocon III 5 m

ICS 11.040.70

Price based on 3 pages
