DIN EN ISO 11979-1

DIN

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DIN EN ISO 11979-1:2006-10

Ophthalmic implants – Intraocular lenses – Part 1: Vocabulary (ISO 11979-1:2012); English version EN ISO 11979-1:2012, English translation of DIN EN ISO 11979-1:2013-01

Ophthalmische Implantate –
Intraokularlinsen –
Teil 1: Vokabular (ISO 11979-1:2012);
Englische Fassung EN ISO 11979-1:2012,
Englische Übersetzung von DIN EN ISO 11979-1:2013-01

Implants ophtalmiques –
Lentilles intraoculaires –
Partie 1: Vocabulaire (ISO 11979-1:2012);
Version anglaise EN ISO 11979-1:2012,
Traduction anglaise de DIN EN ISO 11979-1:2013-01

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In case of doubt, the German-language original shall be considered authoritative.

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A comma is used as the decimal marker.

National foreword

This document (ISO 11979-1:2012) has been prepared by Technical Committee ISO/TC 172 "Optics and photonics", Subcommittee SC 7 "Ophthalmic optics and instruments" in collaboration with Technical Committee CEN/TC 170 "Ophthalmic optics" (both secretariats are held by DIN, Germany).

The responsible German body involved in its preparation was the *Normenausschuss Feinmechanik und Optik* (Optics and Precision Mechanics Standards Committee), Working Committee NA 027-01-20 AA *Intraokulare Medizinprodukte*.

DIN EN ISO 11979 consists of the following parts, under the general title *Ophthalmic implants — Intraocular lenses*:

— *Part 1: Vocabulary*
— *Part 2: Optical properties and test methods*
— *Part 3: Mechanical properties and test methods*
— *Part 4: Labelling and information*
— *Part 5: Biocompatibility*
— *Part 6: Shelf-life and transport stability*
— *Part 7: Clinical investigations*
— *Part 8: Fundamental requirements*
— *Part 9: Multifocal intraocular lenses*
— *Part 10: Phakic intraocular lenses*

In Germany, use of the symbol "dpt" for dioptre (expressed in m^{-1}) is legally required and this symbol is to be used rather than the symbol D used in other countries.

Amendments

This standard differs from DIN EN ISO 11979-1:2006-10 as follows:

a) Clause 2 "Terms and definitions" has been revised to include accommodating (2.2), multifocal (2.36), aspheric (2.7) and toric (2.72) intraocular lenses;

b) in German, the term *Brechkraft* has been changed to *Brechwert* (dioptric power);

c) in German, the term *Typ der optischen Form* has been changed to *Optik-Formfaktor* (optic shape factor);

d) in German, the term *Anstellhöhe* has been changed to *Wölbungshöhe* (vault height);

e) in German, the term *Nebenwirkung* has been changed to *unerwünschtes Ereignis* (adverse event) (in accordance with Directive 93/42/EEC);

f) the standard is no longer divided into subclauses depending on subject related criteria; all terms are now listed in alphabetical order on the basis of the English version of the ISO reference document. As a guidance to find the corresponding terms in the German language, National Annex NB contains a bilingual glossary in alphabetical order both in German and English;

g) the text of ISO 11979-1:2012 has been adopted in its entirety.

Previous editions

DIN EN ISO 11979-1: 2000-07, 2006-10

National Annex NA
(informative)

Bibliography

DIN EN ISO 11979-2, *Ophthalmic implants — Intraocular lenses — Part 2: Optical properties and test methods*

DIN EN ISO 11979-3, *Ophthalmic implants — Intraocular lenses — Part 3: Mechanical properties and test methods*

DIN EN ISO 11979-4, *Ophthalmic implants — Intraocular lenses — Part 4: Labelling and information*

DIN EN ISO 11979-5, *Ophthalmic implants — Intraocular lenses — Part 5: Biocompatibility*

DIN EN ISO 11979-6, *Ophthalmic implants — Intraocular lenses — Part 6: Shelf-life and transport stability*

DIN EN ISO 11979-7, *Ophthalmic implants — Intraocular lenses — Part 7: Clinical investigations*

DIN EN ISO 11979-8, *Ophthalmic implants — Intraocular lenses — Part 8: Fundamental requirements*

DIN EN ISO 11979-9, *Ophthalmic implants — Intraocular lenses — Part 9: Multifocal intraocular lenses*

DIN EN ISO 11979-10, *Ophthalmic implants — Intraocular lenses — Part 10: Phakic intraocular lenses*

National Annex NB
(informative)

Glossary

Terms, sorted alphabetically in German

Term, German	Term, English	No.
A		
Achsenmarkierung	axis mark	2.8
Addition	addition power	2.5
Akkommodationsbreite	accommodative amplitude	2.3
akkommodierende Intraokularlinse	accommodating intraocular lens	2.2
anhaltendes unerwünschtes Ereignis	persistent adverse event	2.55
Anzeige des Meridians mit dem niedrigsten Brechwert	indicator of meridian with lowest dioptric power	2.25
asphärische Intraokularlinse	aspheric intraocular lens	2.7
astigmatisch neutralisierende Linse	null lens	2.43
Augenimplantationsprüfung	ocular implantation test	2.44
B		
beschleunigte Haltbarkeitsuntersuchung	accelerated shelf-life study	2.1
bestmögliche Prüfperson	best-case subject	2.9
Brechwert des Auges	optical power of the eye	2.47
Brechwert für den Fernvisus	distance power	2.19
Brechwert für den Nahvisus	near power	2.40
Brechwert	dioptric power	2.18
C		
Chargenbericht	device history record	2.16
Cut-off-Wellenlänge	cut-off wavelength	2.14
D		
Dezentrierung der Optik	optic decentration	2.48
Dioptrienstärke (zu vermeiden)	dioptric power	2.18
E		
einteilige Intraokularlinse	one-piece intraocular lens	2.45
F		
Fernpunkt	far point	2.22
Fertigprodukt-Charge	finished intraocular lens lot	2.23
für die klinische Prüfung bestimmtes Medizinprodukt	device intended for clinical investigation	2.17
G		
Gesamtdurchmesser	overall diameter	2.51

Term, German	Term, English	No.
H		
Haltbarkeit	shelf-life	2.63
Haptik	haptic	2.24
Hersteller	manufacturer	2.31
Hinterkammer-Intraokularlinse	posterior chamber intraocular lens	2.58
Hinterkammerlinse	posterior chamber lens	2.58
I		
Implantationsprüfung außerhalb des Auges	non-ocular implantation test	2.42
in situ	*in situ*	2.26
Integrität der Verpackung	package integrity	2.52
Intraokularlinse	intraocular lens	2.27
Intraokularlinsenmodell	intraocular lens model	2.28
K		
Kippung der Optik	optic tilt	2.50
Konfiguration für den Brechwert für den Fernvisus	distance power configuration	2.20
Konfiguration für den Brechwert für den Nahvisus	near power configuration	2.41
kumulierte unerwünschte Ereignisse	cumulative adverse events	2.12
L		
Lagerbehälter	storage container	2.68
Linsenkörper	body	2.10
M		
Materialdegradationsprüfung	material degradation test	2.32
mehrteilige Intraokularlinse	multi-piece intraocular lens	2.37
Meridian mit dem höchsten Brechwert	meridian of highest dioptric power	2.33
Meridian mit dem niedrigsten Brechwert	meridian of lowest dioptric power	2.34
monofokale Intraokularlinse	monofocal intraocular lens	2.35
multifokale Intraokularlinse	multifocal intraocular lens	2.36
N		
Nahpunkt	near point	2.39
Nd-YAG-Laser-Expositionsprüfung	Nd-YAG laser exposure test	2.38
O		
Optik	optic	2.46
Optik-Formfaktor	optic shape factor	2.49
P		
paraxiale Brennweite	paraxial focal length	2.53
Pfeilhöhe	sagittal distance	2.61
phake Intraokularlinse	phakic intraocular lens	2.56
Photostabilitätsprüfung	test of photostability	2.71
Positionierungsbohrung	positioning hole	2.57
Primärverpackung	primary package	2.59
Prüfmaterial	test material	2.70

Term, German	Term, English	No.
Prüfperson, die aus der Nachbeobachtung herausfällt	lost to follow-up subject	2.30
R		
reduzierte Brennweite	reduced focal length	2.60
S		
Sagittalhöhe	sagittal distance	2.61
Scheitel	vertex	2.74
Schlaufe	loop	2.29
selbstklebendes Etikett	self-adhesive label	2.62
Sonderanfertigung eines Medizinprodukts	custom-made device	2.13
sphärische Intraokularlinse	spherical intraocular lens	2.65
sphärisches Äquivalent	spherical equivalent	2.64
sphärisches Äquivalent	spherical equivalent power	2.64
Stabilität	stability	2.66
Sterilisationscharge	sterilization load	2.67
subjektive Refraktion	subjective refraction	2.69
T		
torische Intraokularlinse	toric intraocular lens	2.72
U		
Ursprungsmodell einer Intraokularlinse	parent intraocular lens model	2.54
V		
Verfallsdatum	expiration date	2.21
Vorderkammer-Intraokularlinse	anterior chamber intraocular lens	2.6
Vorderkammerlinse	anterior chamber lens	2.6
W		
wirksame Optik	clear optic	2.11
Wölbungshöhe	vault height	2.73
Z		
zusätzliche Verpackung	additional wrapping	2.4
Zylinder	cylindrical power	2.15
Zylinderwert	cylindrical power	2.15

Terms, sorted alphabetically in English

Term, English	Term, German	No.
A		
accelerated shelf-life study	beschleunigte Haltbarkeitsuntersuchung	2.1
accommodating intraocular lens	akkommodierende Intraokularlinse	2.2
accommodative amplitude	Akkommodationsbreite	2.3
additional wrapping	zusätzliche Verpackung	2.4
addition power	Addition	2.5
anterior chamber lens	Vorderkammerlinse	2.6
anterior chamber intraocular lens	Vorderkammer-Intraokularlinse	2.6
aspheric intraocular lens	asphärische Intraokularlinse	2.7
axis mark	Achsenmarkierung	2.8
B		
best-case subject	bestmögliche Prüfperson	2.9
body	Linsenkörper	2.10
C		
clear optic	wirksame Optik	2.11
cumulative adverse events	kumulierte unerwünschte Ereignisse	2.12
custom-made device	Sonderanfertigung eines Medizinprodukts	2.13
cut-off wavelength	Cut-off-Wellenlänge	2.14
cylindrical power	Zylinder, Zylinderwert	2.15
D		
device history record	Chargenbericht	2.16
device intended for clinical investigation	für die klinische Prüfung bestimmtes Medizinprodukt	2.17
dioptric power	Brechwert	2.18
distance power	Brechwert für den Fernvisus, Basis-Brechwert	2.19
distance power configuration	Konfiguration für den Brechwert für den Fernvisus	2.20
E		
expiration date	Verfallsdatum	2.21
F		
far point	Fernpunkt	2.22
finished intraocular lens lot	Fertigprodukt-Charge	2.23
H		
haptic	Haptik	2.24
I		
indicator of meridian with lowest dioptric power	Anzeige des Meridians mit dem niedrigsten Brechwert	2.25
in situ	*in situ*	2.26
intraocular lens	Intraokularlinse	2.27
intraocular lens model	Intraokularlinsenmodell	2.28

Term, English	Term, German	No.
L		
loop	Schlaufe	2.29
lost to follow-up subject	Prüfperson, die aus der Nachbeobachtung heraus-fällt	2.30
M		
manufacturer	Hersteller	2.31
material degradation test	Materialdegradationsprüfung	2.32
meridian of highest dioptric power	Meridian mit dem höchsten Brechwert	2.33
meridian of lowest dioptric power	Meridian mit dem niedrigsten Brechwert	2.34
monofocal intraocular lens	monofokale Intraokularlinse	2.35
multifocal intraocular lens	multifokale Intraokularlinse	2.36
multi-piece intraocular lens	mehrteilige Intraokularlinse	2.37
N		
Nd-YAG laser exposure test	Nd-YAG-Laser-Expositionsprüfung	2.38
near point	Nahpunkt	2.39
near power	Brechwert für den Nahvisus	2.40
near power configuration	Konfiguration für den Brechwert für den Nahvisus	2.41
non-ocular implantation test	Implantationsprüfung außerhalb des Auges	2.42
null lens	astigmatisch neutralisierende Linse	2.43
O		
ocular implantation test	Augenimplantationsprüfung	2.44
one-piece intraocular lens	einteilige Intraokularlinse	2.45
optic	Optik	2.46
optical power of the eye	Brechwert des Auges	2.47
optic decentration	Dezentrierung der Optik	2.48
optic shape factor	Optik-Formfaktor	2.49
optic tilt	Kippung der Optik	2.50
overall diameter	Gesamtdurchmesser	2.51
P		
package integrity	Integrität der Verpackung	2.52
paraxial focal length	paraxiale Brennweite	2.53
parent intraocular lens model	Ursprungsmodell einer Intraokularlinse	2.54
persistent adverse event	anhaltendes unerwünschtes Ereignis	2.55
phakic intraocular lens	phake Intraokularlinse	2.56
positioning hole	Positionierungsbohrung	2.57
posterior chamber lens	Hinterkammerlinse	2.58
posterior chamber intraocular lens	Hinterkammer-Intraokularlinse	2.58
primary package	Primärverpackung	2.59
R		
reduced focal length	reduzierte Brennweite	2.60
S		
sagittal distance	Pfeilhöhe, Sagittalhöhe	2.61
self-adhesive label	selbstklebendes Etikett	2.62

Term, English	Term, German	No.
shelf-life	Haltbarkeit	2.63
spherical equivalent	sphärisches Äquivalent	2.64
spherical equivalent power	sphärisches Äquivalent	2.64
spherical intraocular lens	sphärische Intraokularlinse	2.65
stability	Stabilität	2.66
sterilization load	Sterilisationscharge	2.67
storage container	Lagerbehälter	2.68
subjective refraction	subjektive Refraktion	2.69
T		
test material	Prüfmaterial	2.70
test of photostability	Photostabilitätsprüfung	2.71
toric intraocular lens	torische Intraokularlinse	2.72
V		
vault height	Wölbungshöhe	2.73
vertex	Scheitel	2.74

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11979-1

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English Version

Ophthalmic implants - Intraocular lenses - Part 1: Vocabulary (ISO 11979-1:2012)

Implants ophtalmiques - Lentilles intraoculaires - Partie 1: Vocabulaire (ISO 11979-1:2012)

Ophtalmische Implantate - Intraokularlinsen - Teil 1: Vokabular (ISO 11979-1:2012)

This European Standard was approved by CEN on 14 September 2012.

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Contents

Foreword

This document (EN ISO 11979-1:2012) 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 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

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

This document supersedes EN ISO 11979-1:2006.

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Endorsement notice

The text of ISO 11979-1:2012 has been approved by CEN as a EN ISO 11979-1:2012 without any modification.

1 Scope

This part of ISO 11979 defines terms applicable to intraocular lenses and to the methods used to evaluate them.

NOTE Terms are given alphabetically.

2 Terms and definitions

2.1
accelerated shelf-life study
stability study designed to increase the rate of chemical or physical degradation of a product by using exaggerated storage conditions (e.g. temperature, humidity) to determine kinetic degradation parameters to predict the tentative expiration dating period

2.2
accommodating intraocular lens
AIOL
intraocular lens which provides continuous focusing from far point to near point by changing the dioptric power of the eye

2.3
accommodative amplitude
difference in refractive power between the near point and the far point of the eye

2.4
additional wrapping
container used in addition to the primary packaging and which could be used to maintain sterility of the intraocular lens

2.5
addition power
difference between the distance power and the near power of the lens portion, measured under specified conditions

2.6
anterior chamber lens
anterior chamber intraocular lens
intraocular lens designed to be placed entirely in the anterior chamber of the eye

2.7
aspheric intraocular lens
intraocular lens having at least one surface with a monotonically continuously variable curvature from the vertex to the periphery

2.8
axis mark
indicator of the meridian of lowest optical power

2.9
best-case subject
subject with no pre-operative ocular pathology, no macular degeneration detected at any time, and no previous surgery for the correction of refractive errors

2.10
body
central part of an intraocular lens incorporating the optic

See Figure 1.

2.11
clear optic
diameter of a circle concentric with the optical axis of an intraocular lens, containing only features of the intraocular lens belonging to the optical design

See Figure 1.

2.12
cumulative adverse events
total number of adverse events that have occurred at any time up to a specified time point postoperatively

2.13
custom-made device
any device specifically made in accordance with a duly qualified medical practitioner's written prescription, which gives, under his responsibility, specific design characteristics and is intended for the sole use of a particular patient

NOTE Mass-produced devices, which need to be adapted to meet the specific requirements of the medical practitioner, are not considered to be custom-made.

2.14
cut-off wavelength
minimum wavelength at which the transmission reaches and remains below a defined level

2.15
cylindrical power
difference in dioptric power between the meridians with the highest and the lowest dioptric powers

2.16
device history record
collection of records and reports assembled in a batch package, containing, or referring to, the relevant information pertaining to the manufacture and control of that batch of devices

2.17
device intended for clinical investigation
any device intended for use by a duly qualified medical practitioner when conducting a clinical investigation

2.18
dioptric power
reciprocal of the reduced paraxial focal length *in situ* for light with a wavelength of 546,07 nm, where paraxial focal length is the distance between the back principal plane and the back paraxial focal point, and reduced paraxial focal length is the paraxial focal length divided by the refractive index of the surrounding medium

NOTE The unit for expressing dioptric power is the reciprocal metre (m^{-1}). The special name for this unit is "dioptre", for which the symbol "D" is used.

2.19
distance power
base power
far power
power that is intended to provide an in-focus image of an object at infinite distance

2.20
distance power configuration
configuration of an accommodating intraocular lens in the eye that is intended to result in a distant object being in focus in the retinal plane

2.21
expiration date
termination of shelf-life, after which the intraocular lens is not to be used

2.22
far point
point at infinity that is focussed on the fovea of an eye

2.23
finished intraocular lens lot
specific quantity of intraocular lenses that is intended to have uniform characteristics and quality, within specified limits, and which is produced according to a single manufacturing order or during the same cycle of manufacture and which is packaged, labelled and sterilized

2.24
haptic
non-optical, generally peripheral component of an intraocular lens intended to keep the lens in place in the eye

2.25
indicator of meridian with lowest dioptric power
physical identification of the meridian with the lowest dioptric power

2.26
in situ
in equilibrium with aqueous humour at 35 °C ± 2 °C

2.27
Intraocular lens
IOL
ophthalmic lens intended for implantation inside the eye

2.28
intraocular lens model
identification by which the features of an intraocular lens, including its body (e.g. body diameter, optic diameter, optic shape factor) and its loops (e.g. configuration, calibre, angulation), and the material(s) used in its construction have been fully specified

NOTE Any significant change in the specification of the materials (including their formulation or synthesis procedures) will result in it being considered a new model.

2.29
loop
peripheral extension on the body serving to position the intraocular lens in the eye

NOTE Loops are parts of the haptic (2.24) or can be the haptic.

2.30
lost-to-follow-up subject
subject for which the final post-operative case report form is overdue and who cannot be contacted despite extensive written and telephone follow-ups to determine the final clinical outcome

NOTE This category does not include subjects who died.

2.31
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

NOTE The obligations to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels a product with a view to its being placed on the market under his own name.

2.32
material degradation test
test that determines the potential for degradation of a material

2.33
meridian of highest dioptric power
meridian with the most positive or least negative dioptric power which is orthogonal to that defined in 2.34

2.34
meridian of lowest dioptric power
meridian with the least positive or most negative dioptric power which is orthogonal to that defined in 2.33

2.35
monofocal intraocular lens
intraocular lens with two rotationally symmetric optical surfaces having one primary focus

2.36
multifocal intraocular lens
MIOL
intraocular lens having two or more foci

2.37
multi-piece intraocular lens
intraocular lens assembled from separate loop and body components

NOTE An intraocular lens with a body and two loops is often referred to as a three-piece intraocular lens.

2.38
Nd-YAG laser exposure test
test that determines the physical and chemical effects of Nd-YAG laser exposure on a test material

2.39
near point
nearest distance at which one can focus on an object

2.40
near power
power that is intended to provide an in-focus image of a near object

2.41
near power configuration
configuration of an accommodating intraocular lens in the eye that is intended to result in a near-object in-focus in the retinal plane

2.42
non-ocular implantation test
test that evaluates the reciprocal tolerance of a test material and local tissue after implantation of the test material in a non-ocular site in an animal

2.43
null lens
lens used to neutralize toric lens cylinder power

2.44
ocular implantation test
test that evaluates the reciprocal tolerance of a test material and local tissue after implantation into the anterior segment of the eye of an appropriate animal

2.45
one-piece intraocular lens
intraocular lens where the haptic forms an integral part with the body

2.46
optic
image-forming, generally central component of an intraocular lens

2.47
optical power of the eye
reciprocal of the reduced focal length of an eye

2.48
optic decentration
lateral displacement of the optic due to compression of the haptic(s), measured as the distance between the geometrical centre of the clear optic and the centre of a cylinder of prescribed diameter to which the intraocular lens is confined

2.49
optic shape factor
term associated with the curvatures of the refracting surfaces of the optic (e.g. plano-convex, bi-convex)

NOTE The optic shape factor is determined using the following equation:

$$S = \frac{R_1 + R_2}{R_1 - R_2}$$

where

S is the optic shape factor,

R_1 is the vertex radius of the anterior surface with respect to the eye,

R_2 is the vertex radius of the posterior surface with respect to the eye.

2.50
optic tilt
angle between the optical axis in the uncompressed state and that in the compressed state, with the intraocular lens confined to a prescribed diameter

2.51
overall diameter
diameter of the cylinder circumscribing an intraocular lens, just making contact with it, be it the haptic or optic, the axis of the cylinder being coincident with the optical axis of the intraocular lens

See Figure 1.

2.52
package integrity
container's ability to protect the intraocular lens from contamination

2.53
paraxial focal length
distance between the back principal plane and the back paraxial focal point

2.54
parent intraocular lens model
intraocular lens model that a manufacturer has qualified based on a clinical investigation of at least 100 subjects and which has met the requirements of all parts of ISO 11979

2.55
persistent adverse event
adverse event that is present at the conclusion of a clinical investigation

2.56
phakic intraocular lens
PIOL
intraocular lens, the primary indication for which is the modification of the refractive power of a phakic eye

2.57
positioning hole
hole, whether penetrating or not, intended to be used for surgical manipulation

See Figure 1.

2.58
posterior chamber lens
posterior chamber intraocular lens
intraocular lens designed to be placed entirely in the posterior chamber of the eye

2.59
primary package
container that physically and directly protects the intraocular lens and which could maintain sterility

2.60
reduced focal length
focal length divided by the refractive index of the medium in image space

2.61
sagittal distance
maximum distance between the planes, normal to the optical axis, which contact, respectively, the most anterior and the most posterior points, be it the haptic or optic, of an uncompressed intraocular lens

See Figure 1.

2.62
self-adhesive label
label included in the storage container for hospital record use

2.63
shelf-life
period during which an intraocular lens remains suitable for implantation in the human eye

2.64
spherical equivalent
spherical equivalent power
mean of the dioptric powers in the meridians with the highest and lowest dioptric powers

2.65
spherical intraocular lens
intraocular lens in which both surfaces consist of a segment from a sphere

2.66
stability
extent to which a product retains properties and characteristics within the manufacturer's specified limits, throughout its period of storage, i.e. its shelflife

2.67
sterilization load
products to be, or that have been, sterilized together using a given sterilization process

2.68
storage container
packaging intended to protect the device during storage and distribution

2.69
réfraction subjective
correction à la fois sphérique et cylindrique qui optimise l'acuité visuelle d'un sujet en se fondant sur ses réponses et le procédé de détermination de cette correction

2.70
test material
sterile finished intraocular lens, as intended for human implantation, or representative sample material manufactured and processed using a procedure equivalent to that used for the intraocular lens

NOTE If using intraocular lenses as the test material, it is preferable to choose lenses with powers within ± 2 D of the mean of the power range, e.g. in general 18 D to 22 D.

2.71
test of photostability
test that determines the potential for degradation of a test material due to exposure to light

2.72
toric intraocular lens
TIOL
intraocular lens having different powers in orthogonal meridian

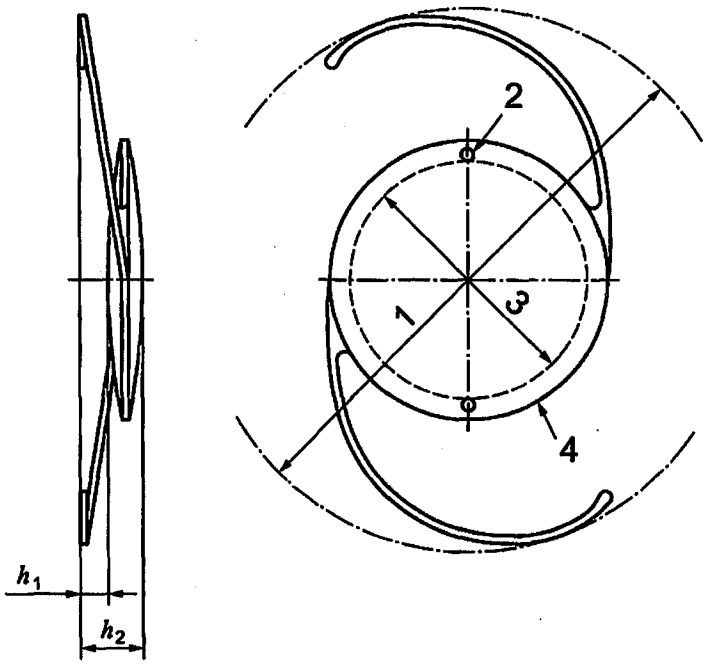
2.73
vault height
distance from a plane normal to the optical axis, containing the point most proximal to the iris of the uncompressed haptic of an intraocular lens, to the plane normal to the optical axis, containing the vertex of the iris proximal surface

See Figure 1.

NOTE 1 The iris proximal side of the intraocular lens refers to the intended position as implanted.

NOTE 2 The vault height is positive if the distance defined is in the direction towards the retina when implanted, and negative if not.

2.74
vertex
point of intersection of the optical axis with the surface of a lens



Key

1 overall diameter
2 positioning hole
3 clear optic
4 body
h_1 vault height
h_2 sagittal distance

Figure 1 — Overall diameter, vault height, sagittal distance, clear optic, body and positioning hole

Bibliography

[1] ISO 11979 (all parts), *Ophthalmic implants — Intraocular lenses*