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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN ISO 11979-1

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ICS 01.040.11; 11.040.70

Supersedes EN ISO 11979-1:2006

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)

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COMITÉ EUROPÉEN DE NORMALISATION  
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## 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of an identical text or by endorsement, at the latest by March 2013, and conflicting national standards shall be withdrawn at the latest by March 2013.

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## **Ophthalmic implants — Intraocular lenses —**

### **Part 1: Vocabulary**

#### **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

## **Implants ophthalmiques — Lentilles intraoculaires —**

### **Partie 1: Vocabulaire**

#### **1 Domaine d'application**

La présente partie de l'ISO 11979 définit les termes applicables aux lentilles intraoculaires et aux méthodes d'essai utilisées pour les évaluer.

NOTE Les termes sont donnés par ordre alphabétique de la version anglaise.

#### **2 Termes et définitions**

##### **2.1**

###### **étude en accéléré de la durée de conservation**

modalités de stabilité définies pour augmenter la vitesse de dégradation physique ou chimique d'un produit en utilisant des conditions de stockage exagérées (par exemple température, humidité) afin de déterminer des paramètres cinétiques de dégradation pour définir une date de péremption provisoire

##### **2.2**

###### **lentille intraoculaire accommodative**

###### **LIOA**

lentille intraoculaire qui assure une mise au point continue d'un point éloigné vers un point proche en modifiant la puissance dioptrique de l'œil

##### **2.3**

###### **amplitude d'accommodation**

différence de puissance de réfraction entre le point proche et le point éloigné de l'œil

##### **2.4**

###### **emballage complémentaire**

emballage utilisé en complément de l'emballage primaire et qui peut éventuellement servir à maintenir la stérilité de la lentille