



**NSAI**

# Quality System Approval Certificate

## Medical Devices Directive 93/42/EEC

*The National Standards Authority of Ireland as a duly designated  
Notified Body, (identification number 0050), for the purposes of the European Communities  
(Medical Devices) Regulations (S.I. No. 252 of 1994)*

**APPROVES THE QUALITY SYSTEM APPLIED BY**

### HexaVision SARL

**3 rue du Colonel Moll - 75017  
Paris  
France**

*to the Product Family*

### Posterior Chamber Intraocular Lenses, Hydrophilic Acrylic, Pseudophakic

**GMDN Code: 35658**

*on the basis of examination under the requirements of Directive 93/42/EEC on Medical Devices, Annex  
II, excluding (4)*

*The use of the NSAI Notified Body identification number 0050 in conjunction with CE Marking of  
Conformance for this product family is hereby authorised.*

<b>Registration Number:</b>	<b>252.699</b>
<b>Original Approval:</b>	<b>29 May 2006</b>
<b>Last Amended on:</b>	<b>03 December 2019</b>
<b>Remains valid until:</b>	<b>01 August 2021</b>

**Signed:**

Approved by:  
Geraldine Larkin  
Chief Executive Officer, NSAI

Approved by:  
Elaine Darcy  
European Medical Device Operations Manager

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**  
Details of the operational locations included within the scope of this approval can be obtained from NSAI

In the case of a Class III device, this certificate must be supported by a valid design examination certificate

**National Standards Authority of Ireland, 1 Swift Square, Northwood, Santry, Dublin 9, Ireland.**