

**NSAI**

# EC Design Examination 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)*

**HAS EXAMINED THE DESIGN DOSSIER**

**Submitted by**

**Aaren Scientific Inc.**

**1040 South Vintage Avenue, Bldg A**

**Ontario**

**CA 91761**

**USA**

*For Product Family*

**Posterior Chamber Intraocular Lens, Heparin Surface Modified,  
Pseudophakic.**

**GMDN Code: 35658**

**CONCLUSION of EXAMINATION:**

*NSAI have performed an examination of the design dossier relating to the above named product family and  
conclude that the design complies with the requirements of Directive 93/42/EEC on Medical Devices, Annex II (4)*

**Registration Number: 252.677**

**Original Approval: 07 December 2006**

**Last Amended on: 13 November 2018**

**Remains valid until: 11 July 2023**

**Signed:**

Approved by:  
Geraldine Larkin  
Chief Executive Officer, NSAI

Approved by:  
Susan Murphy  
European Medical Device Operations Manager

**CONDITIONS OF VALIDITY:**

**This certificate remains valid on condition that the Approved Quality System is maintained in an adequate and efficacious manner.**

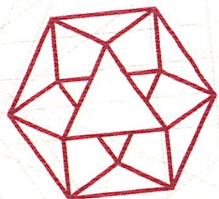
**Approved model numbers are included in the associated attachment**

**Note: Not valid without a valid Annex II Section 3 Certificate.**

**Changes which could affect conformity with the essential requirements of Directive 93/42/EEC or with the conditions prescribed for use of the  
product must receive further approval from NSAI.**

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





# NSAI

## Attachment to Certificate 252.677 dated 07 December 2006

This Certificate covers 8 model(s)

Model Reference	Detail
BioVue	Small Incision, Heparin, 1 pc Biconvex, Modified C, 1391
BioVue 3	Small Incision, Heparin, 3 pc Biconvex, Modified C, 1361
BioVue 4	Small Incision, Heparin, 1 pc Biconvex, Foot Plate 4pt, 1363
BioVue PAL	Small Incision, Heparin Aspheric, 1-pc Biconvex, Modified C, 1381
BioVue 3 PAL	Small Incision, Heparin Aspheric, 3-pc Biconvex, Modified C, 1487
BioVue 4V PAL	Small Incision, Heparin Aspheric, 1-pc Biconvex, Modified C, 1497
HSP-55B	1-pc Bcvx, Modified C, 1253
HSP-65A2	1-pc Bcvx, Modified C, 1254