

## **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

## Aaren Scientific Inc.

1040 South Vintage Avenue, Bldg A Ontario CA 91761 USA

to the Product Family

## Posterior Chamber Intraocular Lens, Heparin Surface Modified, 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.

**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

Geraldine Larkin
Chief Executive Officer, NSAI

1) 113m

Approved by: Susan Murphy

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.