EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60130765 0001

Report No.: 12031321 002

Manufacturer:
Advanced Ophthalmic Innovations
Pte. Ltd.
101 Cecil Street
#25-04 Tong Eng Building
Singapore 069533
Singapore

Products:
Glaucoma Implant

(see attachment for additional site included)

Replaces Approval, Registration No.: HD 60118700 0001

Expiry Date: 2022-03-22

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2018-08-20

Date: 2018-08-20

Notified Body

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60130765 0001
Report No.: 12031321 002

Manufacturer:
Advanced Ophthalmic Innovations Pte. Ltd.
101 Cecil Street
#25-04 Tong Eng Building
Singapore 069533
Singapore

Site included:

Block 79 Ayer Rajah Crescent,
#05-01/04 A*Start Central, Singapore 139955

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2018-08-20

M.Aihara

M.Sc. M. Aihara