EC Certificate

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

Registration No.: HD 60148953 0001

Report No.: 21250656 021

Manufacturer:
Cutting Edge SAS
770, Rue Alfred Nobel, Immeuble le Nobel
34000 Montpellier
France

Products:
Intraocular lenses

(see attachment for additional sites included)

Replaces Certificate, Registration No.: HD 60116293 0001

Expiry Date: 2024-05-26

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: 2020-04-24

Date: 2020-04-24

Notified Body

Dipl.-Ing. I. Munkler

TÜV Rheinland LGA Products GmbH - Zertifizierungsstelle

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.

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60148953 0001
Report No.: 21250656 021

Manufacturer: Cutting Edge SAS
770, Rue Alfred Nobel, Immeuble le Nobel
34000 Montpellier
France

Sites included:

Cutting Edge Manufacturing SAS
580 rue Max Planck
31670 Labège
France

Cutting Edge Manufacturing SAS
4099 La Lauragaise
31670 Labège
France

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland I

Dipl.-Ing. I. Munkler

Date: 2020-04-24

10/020 h 04.08 ® TÜV, TUEV and TUV are registered trademarks. Utilisation and application requires prior approval.