

EC Certificate

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

Registration No.: HD 60116293 0001

Report No.: 21250656 002

Manufacturer: Cutting Edge SAS

770, Rue Alfred Nobel, Immeuble le Nobel

34000 Montpellier

France

Products: - intraocular lens

(see attachment for additional sites included)

Expiry Date: 2021-12-07

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 a LGA Re-

Effective Date: 2017-02-20

Date: 2017-02-20

Notified Body

Dr. K. Kluge

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.



TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Doc. 1/1, Rev. 0

Attachment to Certificate

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HD 60116293 0001

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21250656 002

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

Activities: Design and development and manufacture.

Cutting Edge Manufacturing SAS 4099 La Lauragaise 31670 Labège France

Activities: Distribution.

Notified Body

Date: 2017-02-20