EC Certificate

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

Registration No.: HD 60140485 0001

Report No.: 21259653 013

Manufacturer:
HumanOptics AG
Spardorfer Str. 150
91054 Erlangen
Deutschland

Products: Ophthalmological devices

(see attachment for products and additional sites included)

Replaces Certificate, Registration No.: HD 60118853 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.

Notified Body

Effective Date: 2019-07-08

Date: 2019-07-08

Roland Gruber

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.

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Doc. 1/1, Rev. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60140485 0001
Report No.: 21259653 013

Manufacturer: HumanOptics AG
Spardorfer Str. 150
91054 Erlangen
Deutschland

Products included:

- Lenses, intraocular, posterior chamber; material: Acrylate
- Artificial irides
- Iris diaphragms

Sites included:

- HumanOptics AG
  Westerwaldstr. 11-13
  53757 Sankt Augustin, Germany

- HumanOptics AG
  Westerwaldstr. 16-16a
  53757 Sankt Augustin, Germany

Notified Body

Date: 2019-08-01

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle