EC Certificate

TÜVRheinland®

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

Registration No.: HD 2339954-1

Manufacturer: HumanOptics Holding AG
Spardorfer Str. 150
91054 Erlangen
Germany

Products: Ophthalmological devices

Products included:

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

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.

Report No.: 1087913-10

Effective date: 2021-05-21

Expiry date: 2024-05-26

Issue date: 2021-05-21

TÜV Rheinland LGA Products GmbH TÜVRheinland

Dipl.-Ing. S. Pane
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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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91054 Erlangen
Germany

The scope of certification includes the following manufacturing sites:

No.	Location
/01	HumanOptics Holding AG Spardorfer Str. 150 91054 Erlangen Germany
/02	HumanOptics Holding AG Westerwaldstr. 11-13 53757 Sankt Augustin Germany
/03	HumanOptics Holding AG Westerwaldstr. 16-16a 53757 Sankt Augustin Germany

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