



TÜVRheinland®

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

**Registration No.:** HD 60118853 0001

**Report No.:** 21259653 001

**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 60090272 0001

**Expiry Date:** 2021-09-29

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:** 2017-04-13

**Date:** 2017-04-13



Notified Body

*Fabian Bley*  
Dipl.-Ing. F. Bley

**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**

**Attachment to  
Certificate**

**Registration No.:** HD 60118853 0001  
**Report No.:** 21259653 004

**Manufacturer:** HumanOptics AG  
Spardorfer Str. 150  
91054 Erlangen  
Deutschland

**Products included:**

Lenses, intraocular, posterior chamber; material:

- PMMA
- Acrylate

Lenses, intraocular, anterior chamber; material:

- PMMA

Graft capsular tension rings; material:

- PMMA

Artificial irides

Iris diaphragms

**Date:** 2018-02-27

**Notified Body**

**Roland Gruber**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60118853 0001  
**Report No.:** 21259653 004

**Manufacturer:** HumanOptics AG  
Spardorfer Str. 150  
91054 Erlangen  
Deutschland

**Site included:**

HumanOptics AG  
Westerwaldstr. 11-13  
53757 St. Augustin  
Germany

HumanOptics AG  
Westerwaldstr. 16-16a  
53757 St. Augustin  
Germany

**Date:** 2018-02-27

**Notified Body**

**Roland Gruber**

