

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

Registration No.: HD 60141442 0001

Report No.: 21237378 016

Manufacturer: Bausch & Lomb GmbH
Im Schuhmachergewann 4
69123 Heidelberg
Deutschland

Products: Instruments and products for ophthalmology
(see attachment for products included)
Replaces Certificate, Registration No.: HD 60107669 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: 2019-08-01

Date: 2019-08-01

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. 1/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60141442 0001
Report No.: 21237378 016

Manufacturer: Bausch & Lomb GmbH
Im Schuhmachergewann 4
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Products included:

- Cannula Irrigation and/or Aspiration incl. accessories
- Bipolar Forceps and Eraser incl. accessories
- Blades, sterile for single use
- Trephines, sterile for single use
- Per Procedure Tray (PPT) Cataract, sterile for single use
- Corneal Irrigator, sterile for single use
- Eye Speculum with and without aspiration, sterile for single use
- Forceps, sterile for single use
- Irrigation Aspiration Handpiece, sterile for single use
- Manipulator, sterile for single use
- Per Procedure Tray Vitreoretinal (PPT VR), sterile for single use

Date: 2019-08-01

Notified Body


Dr. K. Kluge



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/2, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60141442 0001
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Manufacturer: Bausch & Lomb GmbH
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Products included:

- Bipolar Eraser, sterile for single use
- Forceps Vitreoretinal, sterile for single use
- Membrane Pick, sterile for single use
- Böhnke Donor Cornea Holder, sterile for single use
- Passive Aspiration Handpiece and Backflush/Extrusion Handpiece, sterile for single use

For the following devices the scope covers only the aspects of the manufacture concerned with the securing and maintaining sterile conditions:

- Eye Shield, sterile

Date: 2019-08-01

Notified Body

Dr. K. Kluge
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