# 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 Zertifizierungsstelle

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

**Attachment to Certificate**
**Registration No.:** HD 60141442 0001
**Report No.:** 21237378 016

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

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

**Notified Body**

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

**Date:** 2019-08-01

Dr. K. Kluge

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Doc. 2/2, Rev. 0

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

**Attachment to Certificate**
**Registration No.:** HD 60141442 0001
**Report No.:** 21237378 016

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

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

**Notified Body**

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dr. K. Kluge

**Date:** 2019-08-01

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