

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

has established and applies a quality management system for medical devices
for the following scope:

**Design, development, manufacture, installation, servicing
and distribution of medical devices**
(see attachment for products and additional sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-11-09
Certificate Registration No.: SX 60133519 0001
An audit was performed. Report No.: 31892411 001
This Certificate is valid until: 2021-10-18

Certification Body



Date 2018-11-09



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 1/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60133519 0001
Report No.: 31892411 001

Organization: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Scope:

Devices included:

- Manual Surgical Instruments for Ophthalmology, Otolaryngology and Plastic- and Reconstructive procedures
- Ophthalmic Surgical Equipment
- Procedure Packs for use with Ophthalmic Surgical Equipment during Cataract and Vitreoretinal procedures
- Intraocular Lenses and Insertion Devices
- Viscoelastics and Retinal Tamponades

Certification Body



Date: 2018-11-09



Roland Gruber



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60133519 0001
Report No.: 31892411 001

Organization: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Scope: Sites included:

Bausch + Lomb, Incorporated
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122 USA with
499 Sovereign Court
Manchester, MO 63011 USA

Activities associated with the design and development,
manufacture, installation, servicing and distribution of:

- Manual Surgical Instruments for Ophthalmology,
Otolaryngology and Plastic- and Reconstructive procedures
- Ophthalmic Surgical Equipment
- Procedure Packs for use with Ophthalmic Surgical
Equipment during Cataract and Vitreoretinal procedures

Certification Body



Date: 2018-11-09



Roland Gruber



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60133519 0001
Report No.: 31892411 001

Organization: Bausch + Lomb, Incorporated
1400 North Goodman St.
Rochester NY 14609
USA

Scope: Sites included:

Bausch + Lomb, Incorporated
21 Park Place Blvd. N.
Clearwater, FL 33759 USA

Activities associated with the design and development,
and manufacture of:
- Intraocular Lenses and Insertion Devices

Certification Body



Date: 2018-11-09



Roland Grüber



TÜV Rheinland LGA Products GmbH
TÜVRheinland[®]
Zertifizierungsstelle