TÜVRheinland®

EC Certificate

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

Registration No.: HD 60146676 0001

Report No.: 31892411 015

Manufacturer:

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

Digitally signed by Grabazei Alexandru
Date: 2021.10.27 15:11:06 EEST
Reason: MoldSign Signature
Location: Moldova

Products: Intraocular Lenses and Ophthalmic Devices

(see attachment for products and additional sites included)

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: 2020-10-19

Date: 2020-10-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Balazs Bozsik

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 60146676 0001
Report No.: 31892411 015

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

Additional sites included:

Bausch + Lomb, Incorporated
1501 Graves Mill Road
Lynchburg, VA 24502 USA

Bausch + Lomb, Incorporated
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122 USA

Bausch + Lomb, Incorporated
499 Sovereign Court
Manchester, MO 63011 USA

Bausch + Lomb, Incorporated
50 Technology Drive
Irvine, CA 92618 USA

Date: 2020-10-02

Notified Body

Balazs Bozsik

TÜVRheinland®

Doc. 2/5, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146676 0001
Report No.: 31892411 015

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

Additional sites included:

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

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2020-10-02

Balazs Bozsik

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Doc. 3/5, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146676 0001
Report No.: 31892411 015

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

Products included:

- Viscoelastics, HPMC (Hydroxypropylmethylcellulose)
- Viscoelastics, bacteria fermented
- IOL, Anterior Chamber PMMA Lenses
- IOL, Posterior Chamber PMMA Lenses
- IOL, Posterior Chamber Lenses, Foldable, Softport and Softflex, and Hydropholic Arylic
- IOL, Posterior Chamber Lenses, Foldable, enVista
- IOL, Posterior Chamber Lenses, Foldable, Hydrophobic Arcrylic
- Silicone Oil
- Ophthalmic Microsurgical System, Stellaris
- Ophthalmic Microsurgical System, Stellaris PC
- Ophthalmic Microsurgical Handpieces, for Premiere
- Ophthalmic Microsurgical Handpieces, for Millineum
- Ophthalmic Microsurgical Handpieces, for Stellaris PC
- Ophthalmic Microsurgical Handpieces, for Stellaris

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Date: 2020-10-02

Balazs Bozsik

TÜVRheinland®

Doc. 4/5, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146676 0001
Report No.: 31892411 015

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

Products included:

- Ophthalmic Procedure Packs, with energy driven components for Protégé, Premiere, Millennium
- Ophthalmic Procedure Packs, with energy driven components for Stellaris
- Ophthalmic Procedure Packs, with energy driven components for Stellaris PC
- Non-active Ophthalmic Procedure Packs, for Protégé, Premiere, Millennium
- Non-active Ophthalmic Procedure Packs, for Stellaris
- Non-active Ophthalmic Procedure Packs, for Stellaris PC
- Non-active Ophthalmologic Product, Balanced Salt Solution
- Non-active Ophthalmologic Product, sterile Cannula and Cystotomes
- Non-active Ophthalmologic Product, Laseredge knife
- Non-active Ophthalmologic Product, non-sterile Cystotomes
- Non-active Ophthalmologic Product, Infusion/
- Ophthalmic Microsurgical Handpieces, for Stellaris PC
- Non-sterile Cannula

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierstelle

Notified Body

Balazs Bozsik

Date: 2020-10-02

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60146676 0001
Report No.: 31892411 015

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

Products included:

- Non-active Ophthalmologic Product,
Lens Insertion Device, disposable - use with Silicone IOLs
- Non-active Ophthalmologic Product,
Lens Insertion Device, disposable - use with Acrylic IOLs
- Non-active Ophthalmologic Product
Lens Insertion Device, cartridge with disposable handpiece
- Non-active Ophthalmologic Product,
Lens Insertion Device, cartridge with reusable handpiece
- Non-active Ophthalmologic Product,
- Non-active Ophthalmologic Product, Phaco Needle
- Active Ophthalmic Device, Irregation/Aspiration handpiece
- Active Ophthalmic Device, Bipolar Forceps

For the following devices the scope covers only the aspect of manufacture concerned with conformity of the products with the metrological requirements:
- Markers, Rulers and Gauges

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2020-10-02

Balazs Bozsik

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.

TÜVRheinland®

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 Zertifizierungsstelle

Date: 2019-08-01

Dr. K. Kluge

TÜVRheinland®

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

The State of Maryland

Office of the Secretary of State

This Apostille is not valid for use anywhere within the United States of America, its territories or possessions.

This Apostille does not certify the content of the document for which it is issued.

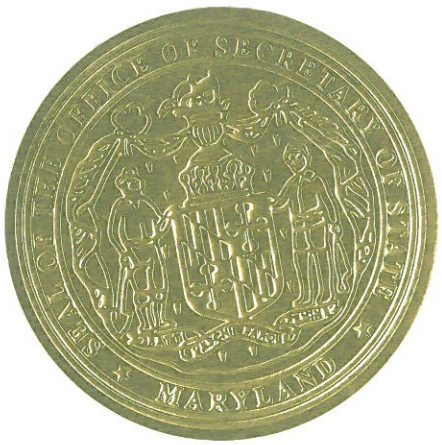
Apostille

(Convention de La Haye du 5 Octobre 1961)

1. Country: United States of America
   This public document
2. has been signed by **Barbara H. Meiklejohn**
3. acting in the capacity of **Clerk of the Circuit Court for Montgomery County**
4. bears the seal/stamp of the **Circuit Court for Montgomery County**

Certified

5. at Annapolis, Maryland
6. the **12th day of June, 2019**
7. by The Secretary of State of Maryland
8. No. 487459
9. Seal



10. Signature

John C. Wohlmuth

Secretary of State

CERTIFICATION

State of Maryland, Montgomery County, Sct.

In the Office of the Clerk of the Circuit Court for Montgomery County

I, Barbara H. Meiklejohn, Clerk of the Circuit Court for Montgomery County, Maryland, a court of record, hereby certify that DINNA KENCANASARI was a commissioned/ appointed and qualified Notary Public commencing on the 27th day of April, 2018.

In Testimony Whereof, I have hereunto set my hand and affixed the seal of the Circuit Court for Montgomery County this 12th day of June, 2019.

Barbara H. Meiklejohn
Clerk of the Circuit Court for Montgomery County

LIC9 20160902

CERTIFICATION

Montgomery county:

I, Budi Isyono, hereby declare that the attached document is satisfactory to the best of my knowledge and belief.

Signatory _____
Budi Isyono

SWORN TO AND SUBSCRIBED before me, a notary public for the State of Maryland, this 11th day of June, 2019.

_____
Dinna Kencanasari

Notary public, State of Maryland

My Commission Expires May 30, 2022

BAUSCH + LOMB
See better. Live better.

RVSS

1400 North Goodman Street
Rochester, NY 14609
585.338.6000
www.bausch.com

Certified True Copy Letter

We, Bausch and Lomb Incorporated, hereby swear (or affirm) that the attached reproduction of Certificate Registration Number:SX 60133519 0001, Quality Management System for Bausch & Lomb Incorporated, 1400 North Goodman Street, Rochester, NY 14609, USA meets the requirements of the standard ISO 13485:2012, and is a true, correct and complete photocopy of the original document on file at Bausch & Lomb Incorporated, 1400 North Goodman Street, Rochester, NY 14609, USA.

Sharon A Tonetta, PhD

Sharon A. Tonetta, Ph.D.
Vice President, Global Regulatory Affairs
Bausch & Lomb Incorporated

10 June 2019
Date

State of New Jersey
County of Union
Subscribed and sworn to (or affirmed) before me on this 10th *day of* June, *2019, by* Sharon A. Tonetta, Ph.D., *proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.*

Rita E. Moore
Signature of Notary Public

STATE OF NOTARY PUBLIC NEW JERSEY
RITA E MOORE
My Commission Expires
September 19, 2019

TÜVRheinland®

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

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

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

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle

TÜVRheinland®

Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

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

DAkkS
Deutsche Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2018-11-09

Roland Gruber

TÜV Rheinland LGA Products GmbH
TÜVRheinland®
Zertifizierungsstelle