

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

Registration No.: HD 60105024 0001

Report No.: 31590993 008

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

Products: Intraocular Lenses and Ophthalmic Devices

(see attachment for products and additional sites included)

Expiry Date: 2020-10-18

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: 2015-10-19

Date: 2015-10-19

Notified Body

Dipl.-Ing. D. Meier



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 60105024 0001
Report No.: 31590993 008

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

Notified Body


Dipl.-Ing. D. Meier



Date: 2016-02-06

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/5, Rev. 1

**Attachment to
Certificate**

Registration No.: HD 60105024 0001
Report No.: 31590993 008

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

Date: 2016-02-06

Notified Body

Dipl.-Ing. D. Meier



TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/5, Rev. 1

**Attachment to
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Registration No.: HD 60105024 0001
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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, Sofport and Soflex, and Hydrophobic Acrylic
- IOL, Posterior Chamber Lenses, Foldable, enVista
- IOL, Posterior Chamber Lenses, Foldable, Hydrophilic Acrylic
- Silicone Oil
- Perfluorocarbons, DK-Line, Okta-Line
- Ophthalmic Microsurgical System, Stellaris
- Ophthalmic Microsurgical System, Stellaris PC
- Ophthalmic Microsurgical Handpieces, for Premiere
- Ophthalmic Microsurgical Handpieces, for Millennium
- Ophthalmic Microsurgical Handpieces, for Stellaris
- Ophthalmic Microsurgical Handpieces, for Stellaris PC

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Registration No.: HD 60105024 0001
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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/non-sterile Cannula

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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,
Independent Viewing Chamber
- Non-active Ophthalmologic Product, Phaco Needle
- Active Ophthalmic Device, Irrigation/Aspiration handpiece
- Active Ophthalmic Device, Bipolar Forceps

For the following devices the scope covers only the aspects
of manufacture concerned with conformity of the products
with the metrological requirements:

- Markers, Rulers and Gauges

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