EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 60146676 0001

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)

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

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.

Report No.: 234163243-20

Effective date: 2021-01-18

Expiry date: 2024-05-26

Issue date: 2021-01-18

TÜV Rheinland Product Safety GmbH
TÜVRheinland®
Zertifizierungsstelle

Song Liu
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 60146676 0001

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

Irvine, CA 92618 USA

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

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 Hydrophilic Acrylic
- IOL, Posterior Chamber Lenses, Foldable, enVista
- IOL, Posterior Chamber Lenses, Foldable, Hydrophobic Acrylic
- 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

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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, Irregation/Aspiration handpiece
- Active Ophthalmic Device, Bipolar Forceps
- Perfluorocarbons, DK-Line, Okta-line

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

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