



**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)

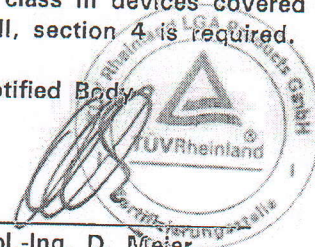
**Expiry Date:** 2020-10-18

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**

Doc. 1/5, Rev. 1

**Attachment to  
Certificate**

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**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:** 2016-02-06

**Notified Body**

**Dipl.-Ing. D. Meier**





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

Doc. 2/5, Rev. 1

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1400 North Goodman St.  
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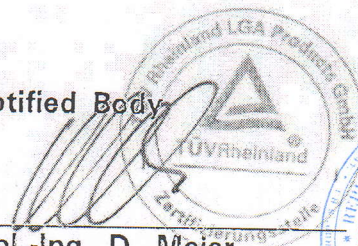
Additional sites included:

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

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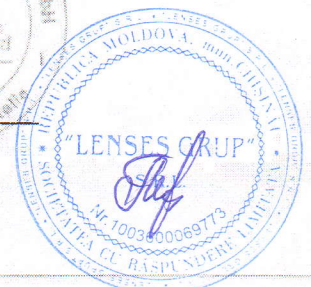
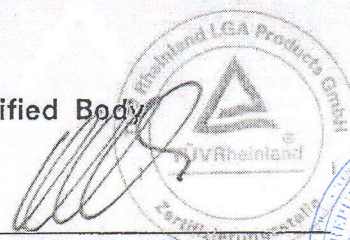
**Products included:**

- 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

**Date:** 2016-02-06

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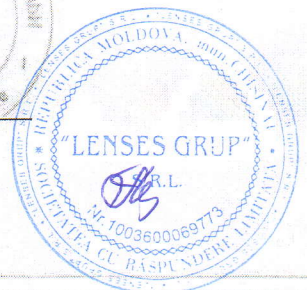
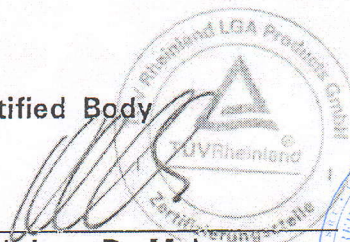
**Products included:**

- 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

**Date:** 2016-02-06

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Manufacturer: Bausch + Lomb, Incorporated  
1400 North Goodman St.  
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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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