



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 020895 0345 Rev. 06

Manufacturer:

Alcon Laboratories, Inc.

6201 South Freeway
Fort Worth, TX 76134-2099
USA

Product Category(ies):

Ophthalmic Implants, Irrigating Solutions, Viscoelastics, Ophthalmic Surgical Disposable Products, Ophthalmic Surgical Procedure Packs, Contact Lens Care Products, Ophthalmic Cutting Instruments, Cannulas, Cystitomes, Surgical Sponges and Sutures, Ophthalmic Solutions and Gels, Surgical Devices and Electrosurgical Products for Use in Ophthalmic Procedures (Cataract, Vitreoretinal, Laser and Imaging), Wavefront Technology Equipment for Ophthalmic Diagnostics and Ophthalmic Devices for the Treatment of Chronic Disease of the Eyelid

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713170911

Valid from:

2020-03-27

Valid until:

2024-05-26

Date,

2020-03-27

Christoph Dicks
Head of Certification/Notified Body

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TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

TÜV SÜD
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A4 / 07.17



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Design Facilities	Products
Alcon Research, LLC 6201 S. Freeway Fort Worth, TX 76134-2099 USA	<ul style="list-style-type: none"> • Viscoelastics • Ophthalmic Surgical Disposable Products • Ophthalmic Surgical Procedure Packs • Ophthalmic Implants • Contact Lens Care Products • Irrigating Solutions • Ophthalmic Cutting Instruments, Cannulas, Cystitomes, Surgical Sponges and Sutures • Ophthalmic Solutions and Gels
Alcon Research, LLC 20511 Lake Forest Dr. Lake Forest, CA 92630 USA	<ul style="list-style-type: none"> • Ophthalmic Implants • Ophthalmic Surgical Disposable Products • Surgical Devices & Electrosurgical Products for Use in Ophthalmic Procedures (Cataract, Vitreoretinal, Laser and Imaging) • Wavefront Technology Equipment for Ophthalmic Diagnostics • Ophthalmic devices for the treatment of chronic disease of the eyelid

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Manufacturing Facilities	Products
Alcon Research, LLC 6201 South Freeway Fort Worth, TX 76134-2099 USA	<ul style="list-style-type: none"> • Contact Lens Care Products • Ophthalmic Solution • Irrigating Solutions
Alcon Research, LLC 6065 Kyle Lane Huntington, WV 25702 USA	<ul style="list-style-type: none"> • Ophthalmic Implants • Surgical Devices
Alcon Research, LLC 9965 Buffalo Speedway Houston, TX 77054-1309 USA	<ul style="list-style-type: none"> • Ophthalmic Surgical Disposable Products • Ophthalmic Surgical Procedure Packs • Surgical Devices & Electrosurgical Products for Use in Ophthalmic Procedures (Cataract, Vitreoretinal, Laser and Imaging)

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<p>Alcon Research, LLC 714 Columbia Avenue, Sinking Spring, PA 19608 USA</p>	<ul style="list-style-type: none"> • Ophthalmic Cutting Instruments, Cannulas, Cystitomes, Surgical Sponges and Sutures • Ophthalmic Implants • Surgical Devices & Electrosurgical Products for Use in Ophthalmic Procedures (Cataract, Vitreoretinal, Laser and Imaging)
<p>Alcon Laboratories Ireland Ltd. Cork Business and Technology Park, Model Farm Road, Cork, Ireland</p>	<ul style="list-style-type: none"> • Ophthalmic Implants
<p>Alcon Research, LLC 2 Vision Lane, Lesage, WV 25537 USA</p>	<ul style="list-style-type: none"> • Surgical Devices
<p>Alcon Singapore Manufacturing Pte. Ltd. 19 Tuas South Avenue 14. Tuas Biomedical Park II, 637313 Singapore, SINGAPORE</p>	<ul style="list-style-type: none"> • Contact Lens Care Products • Ophthalmic Solutions
<p>Alcon Research, LLC 15800 Alton Parkway Irvine, CA 92618-3818 USA</p>	<ul style="list-style-type: none"> • Ophthalmic Surgical Disposable Products • Wavefront Technology Equipment for Ophthalmic Diagnostics • Surgical Devices & Electrosurgical Products for Use in Ophthalmic Procedures (Cataract, Vitreoretinal, Laser and Imaging) • Ophthalmic devices for the treatment of chronic disease of the eyelid

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Alcon Laboratories Belgium Lichterveld 3, 2870 Puurs-St-Amands, BELGIUM	<ul style="list-style-type: none"> Ophthalmic Surgical Procedure Packs
Alcon Research LLC 700 Old Fritztown Road Sinking Spring PA 19608 USA	<ul style="list-style-type: none"> Surgical Devices & Electrosurgical Products for Use in Ophthalmic Procedures (Cataract, Vitreoretinal, Laser and Imaging)

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