



Product Service

# CERTIFICATE

No. Q1N 12 03 20895 258

**Holder of Certificate:** **Alcon Laboratories, Incorporated**

6201 South Freeway  
Fort Worth, TX 76134-2099  
USA

**Certification Mark:**



**Scope of Certificate:** **Design and development, production, distribution, marketing, sales, installation and servicing of Ophthalmic Devices**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:** 713001347

**Valid from:** 2012-04-05

**Valid until:** 2013-06-30

**Date,** 2012-04-10

Hans-Heiner Junker



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TÜV SÜD Product Service GmbH  
Zertifizierstelle  
Ridlerstraße 65 · 80339 München  
Germany



Akkreditiert durch  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln  
und Medizinprodukten  
ZLG-ZQ-999.98.12-46

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Product Service

Attachment to Certificate no Q1N 12 03 20895 258  
dated 2012-04-10

**Applied Standard(s):** EN ISO 13485: 2003/AC: 2009  
Medical Devices-Quality Management Systems-  
Requirements for regulatory purposes

**Design Facility(ies):** Alcon Research Ltd. a subsidiary of Alcon Lab, Inc.  
6201 South Freeway, Fort Worth, TX 76134-2099, USA  
  
Alcon Research Ltd. a subsidiary of Alcon Lab, Inc.  
15800 Alton Parkway, Irvine, CA 92618-3818, USA  
  
Alcon Grieshaber AG  
Winkelriedstrasse 52, 8203 Schaffhausen, Switzerland

**Facility(ies):** Alcon Research Ltd. a subsidiary of Alcon Laboratories, Inc.  
6201 South Freeway, Fort Worth, TX 76134-2099, USA  
  
Alcon Grieshaber AG  
Winkelriedstrasse 52, 8203 Schaffhausen, Switzerland  
  
Alcon Research Ltd. a subsidiary of Alcon Lab, Inc.  
6065 Kyle Lane, Huntington, WV 25702, USA  
  
Alcon Research Ltd.  
2 Vision Lane, Lesage, WV 25537, USA  
  
Alcon Research Ltd. a subsidiary of Alcon Labs Inc.  
9965 Buffalo Speedway, Houston, TX 77054-5008, USA  
  
Alcon Research Ltd. a subsidiary of Alcon Lab, Inc.  
15800 Alton Parkway, Irvine, CA 92618-3818, USA  
  
Alcon Research Ltd. a subsidiary of Alcon Lab, Inc.  
714 Columbia Avenue, Sinking Spring, PA 19608, USA  
  
N.V. Alcon-Couvreur S.A.  
Rijksweg 14, 2870 Puurs, BELGIUM  
  
Alcon Cusi, S.A.  
Camil Fabra 58, Apartado 2, 08320 El Masnou (Barcelona), SPAIN  
  
Laboratoires Alcon S.A.  
23 rue Georges Ferrenbach, 68240 Kaysersberg, FRANCE  
  
Alcon Laboratories Ireland Ltd.  
Model Farm Road, Cork Business and Technological Park, Cork,  
IRELAND  
  
Supplement No. 713002964, Alcon Singapore Manufacturing Pte. Ltd.  
dated 2012 June 07 19 Tuas South Avenue 14, Tuas Biomedical Park II, 637313 Singapore,  
SINGAPORE

Munich, 2012-07-18

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# 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 12 07 20895 259

**Manufacturer:** **Alcon Laboratories, Incorporated**  
6201 South Freeway  
Fort Worth, TX 76134-2099  
USA

**EC-Representative:** **Alcon Laboratories (UK) Ltd.**  
Frimley Business Park  
Frimley, Camberley  
Surrey GU16 7SR  
UNITED KINGDOM

**Product Category(ies):** **Ophthalmic Implants, Electrosurgical Disposable Products, Irrigating Solutions, Viscoelastics, Ophthalmic Surgical Disposable Products, Ophthalmic Surgical Procedure Packs, Contact Lens Care Products, Ophthalmic Cutting Instruments, Cannulae, Cystitomes, Surgical Sponges and Sutures, Ophthalmic Solutions and Gels**

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.:** 713009962

**Valid from:** 2012-10-02

**Valid until:** 2017-04-09

Hans-Heiner Junker

**Date,** 2012-10-09



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

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**Attachment to Certificate No. G1 12 07 20895 259**  
**dated 2012-10-02**  
**Revision 0 – Project 713009962**

Product Service

Design Facilities	Products
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 6201 South Freeway Fort Worth, TX 76134-2099 USA	<ul style="list-style-type: none"> <li>• Viscoelastics</li> <li>• ElectroSurgical Disposable Products</li> <li>• Ophthalmic Surgical Disposable Products</li> <li>• Ophthalmic Surgical Procedure Packs</li> <li>• Ophthalmic Implants</li> <li>• Contact Lens Care Products</li> <li>• Irrigating Solutions</li> <li>• Ophthalmic Cutting Instruments, Cannulae, Cystitomes, Surgical Sponges and Sutures</li> <li>• Ophthalmic Solutions and Gels</li> </ul>
Manufacturing Facilities	Products
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 6201 South Freeway Fort Worth, TX 76134-2099 USA	<ul style="list-style-type: none"> <li>• Contact Lens Care Products</li> <li>• Ophthalmic Solutions</li> </ul>
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 6065 Kyle Lane Huntington, WV 25702 USA	<ul style="list-style-type: none"> <li>• Ophthalmic Implants</li> <li>• Surgical Devices</li> </ul>
N.V. Alcon Couvreur S.A. Rijksweg 14 2870 Puurs, Belgium	<ul style="list-style-type: none"> <li>• Viscoelastics</li> <li>• Contact Lens Care Products</li> <li>• Irrigating Solutions</li> <li>• Ophthalmic Surgical Procedure Packs</li> <li>• Ophthalmic Solutions and Gels</li> </ul>
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 9965 Buffalo Speedway Houston, TX 77054-1309 USA	<ul style="list-style-type: none"> <li>• ElectroSurgical Disposable Products</li> <li>• Ophthalmic Surgical Disposable Products</li> <li>• Ophthalmic Surgical Procedure Packs</li> </ul>
Alcon Cusi S.A. Camil Fabra, 58, Apartado 2 08320 El Masnou (Barcelona), Spain	<ul style="list-style-type: none"> <li>• Contact Lens Care Products</li> <li>• Ophthalmic Solutions</li> </ul>



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Manufacturing Facilities	Products
Laboratoires Alcon S.A. 23, rue Georges Ferrenbach 68240 Kaysersberg, France	<ul style="list-style-type: none"> <li>• Contact Lens Care Products</li> <li>• Ophthalmic Solutions</li> </ul>
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 714 Columbia Avenue Sinking Spring, PA 19608 USA	<ul style="list-style-type: none"> <li>• Ophthalmic Cutting Instruments, Cannulae, Cystitomes, Surgical Sponges and Sutures</li> </ul>
Alcon Laboratories Ireland Ltd. Cork Business and Technology Park Model Farm Road Cork, Ireland	<ul style="list-style-type: none"> <li>• Ophthalmic Implants</li> </ul>
Alcon Research Ltd. 2 Vision Lane Lesage, WV 25537 USA	<ul style="list-style-type: none"> <li>• Surgical Devices</li> </ul>
Alcon Singapore Manufacturing Pte. Ltd. 19 Tuas South Avenue 14, Tuas Biomedical Park II, 637313 Singapore, SINGAPORE	<ul style="list-style-type: none"> <li>• Ophthalmic Solutions</li> <li>• Contact Lens Care Products</li> </ul>

Munich, CRT2, 2012-10-09

Hans-Heiner Junker  
 Certification Medical Technology