



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 17 03 20895 339

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.: 713103523

Valid from: 2017-04-09

Valid until: 2022-04-08

Date, 2017-04-07

Stefan Preiß



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

Page 1 of 5



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 17 03 20895 339**Facility(ies):**

Alcon Research Ltd. a subsidiary of Alcon Lab.Inc.
6201 S. Freeway, Fort Worth, TX 76134-2099, USA

Alcon Research Ltd. a subsidiary of Alcon Lab. Inc
6065 Kyle Lane, Huntington WV 25702, USA

S.A. Alcon-Couvreur N.V.
Rijksweg 14, 2870 Puurs, BELGIUM

Alcon Research Ltd. a subsidiary of Alcon Labs Inc.
9965 Buffalo Speedway, Houston TX 77054-1309, USA

Alcon Cusi, S.A.
Camil Fabra 58, Apartado 2, 08320 El Masnou, SPAIN

Alcon Research, Ltd. a subsidiary of Alcon Lab. Inc.
714 Columbia Avenue, Sinking Spring PA 19608, USA

Alcon Laboratories Ireland Ltd.
Cork Business and Technology Park, Model Farm Road, Cork,
IRELAND

Alcon Research Ltd.
2 Vision Lane, Lesage WV 25537, USA

Alcon Singapore Manufacturing Pte. Ltd.
19 Tuas South Avenue 14, Tuas Biomedical Park II, Singapore
637313, SINGAPORE

Alcon Research Ltd. a subsidiary of Alcon Lab.Inc.
15800 Alton Parkway, Irvine, CA 92618-3818, USA

Transcend Medical, Inc.
127 Independence Drive, Menlo Park CA 94025, USA

**Design
Facility(ies):**

Alcon Research Ltd. a subsidiary of Alcon Lab.Inc.
6201 S. Freeway, Fort Worth, TX 76134-2099, USA

Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc.
20511 Lake Forest Dr., Lake Forest CA 92630, USA

Transcend Medical, Inc.
127 Independence Drive, Menlo Park CA 94025, USA

Page 2 of 5



Attachment to Certificate No. G1.17.03.20895.339
Valid from 2017-04-09
Revision 0 – Project 713103523

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"> • Viscoelastics • ElectroSurgical Disposable Products • Ophthalmic Surgical Disposable Products • Ophthalmic Surgical Procedure Packs • Ophthalmic Implants • Contact Lens Care Products • Irrigating Solutions • Ophthalmic Cutting Instruments, Cannulae, Cystitomes, Surgical Sponges and Sutures • Ophthalmic Solutions and Gels
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 20511 Lake Forest Dr Lake Forrest, CA 92630 USA	<ul style="list-style-type: none"> • Ophthalmic Implants
Transcend Medical Inc. 127 Independence Drive Menlo Park, CA 94025 USA	<ul style="list-style-type: none"> • Ophthalmic Implants

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"> • Contact Lens Care Products • Ophthalmic Solutions
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 6065 Kyle Lane Huntington, WV 25702 USA	<ul style="list-style-type: none"> • Ophthalmic Implants • Surgical Devices



Attachment to Certificate No. G1.17.03.20895.339
Valid from 2017-04-09
Revision 0 – Project 713103523

S.A. Alcon Couvreur N.V. Rijksweg 14 2870 Puurs, Belgium	<ul style="list-style-type: none"> • Viscoelastics • Contact Lens Care Products • Irrigating Solutions • Ophthalmic Surgical Procedure Packs • Ophthalmic Solutions and Gels
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 9965 Buffalo Speedway Houston, TX 77054-1309 USA	<ul style="list-style-type: none"> • ElectroSurgical Disposable Products • Ophthalmic Surgical Disposable Products • Ophthalmic Surgical Procedure Packs
Alcon Cusi S.A. Camil Fabra, 58, Apartado 2 08320 El Masnou (Barcelona), Spain	<ul style="list-style-type: none"> • Contact Lens Care Products • Ophthalmic Solutions
Alcon Research Ltd, a subsidiary of Alcon Laboratories Inc. 714 Columbia Avenue, Sinking Spring, PA 19608 USA	<ul style="list-style-type: none"> • Ophthalmic Cutting Instruments, Cannulae, Cystitomes, Surgical Sponges and Sutures • Ophthalmic Implants
Alcon Laboratories Ireland Ltd. Cork Business and Technology Park, Model Farm Road, Cork, Ireland	<ul style="list-style-type: none"> • Ophthalmic Implants
Alcon Research Ltd. 2 Vision Lane, Lesage, WV 25537 USA	<ul style="list-style-type: none"> • Surgical Devices
Alcon Singapore Manufacturing Pte. Ltd. 19 Tuas South Avenue 14. Tuas Biomedical Park II, 637313 Singapore, SINGAPORE	<ul style="list-style-type: none"> • Contact Lens Care Products • Ophthalmic Solutions
Alcon Research Ltd. a subsidiary of Alcon Laboratories Inc. 15800 Alton Parkway Irvine, CA 92618-3818 USA	<ul style="list-style-type: none"> • Ophthalmic Disposable Surgical Products



Product Service

Attachment to Certificate No. G1.17.03.20895.339
 Valid from 2017-04-09
 Revision 0 – Project 713103523

Transcend Medical, Inc. 127 Independence Drive Menlo Park, CA 94025 USA	<ul style="list-style-type: none"> • Ophthalmic Implants
---	---

Munich, MHS-CRT, 2017-04-07

Stefan Preiß
 Certification Medical Technology