



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.<br>a subsidiary of Alcon Laboratories Inc.<br>6201 South Freeway<br>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> |
| Alcon Research Ltd.<br>a subsidiary of Alcon Laboratories Inc.<br>20511 Lake Forest Dr<br>Lake Forrest, CA 92630 USA  | <ul style="list-style-type: none"> <li>• Ophthalmic Implants</li> </ul>  |
| Transcend Medical Inc.<br>127 Independence Drive<br>Menlo Park, CA 94025 USA  | <ul style="list-style-type: none"> <li>• Ophthalmic Implants</li> </ul>  |

| Manufacturing Facilities  | Products   |
|---|--|
| Alcon Research Ltd.<br>a subsidiary of Alcon Laboratories Inc.<br>6201 South Freeway<br>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.<br>a subsidiary of Alcon Laboratories Inc.<br>6065 Kyle Lane<br>Huntington, WV 25702 USA          | <ul style="list-style-type: none"> <li>• Ophthalmic Implants</li> <li>• Surgical Devices</li> </ul>            |
|   |  |



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

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



Product Service

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

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

Munich, MHS-CRT, 2017-04-07

Stefan Preiß  
 Certification Medical Technology