ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 0393 Rev. 00

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, Vitroretinal, Laser and Imaging), Wavefront Technology Equipment for Ophthalmic Diagnostics and Ophthalmic Devices for the Treatment of Chronic Disease of the Eyelid, Sterile Soft Contact Lenses for Correction of Refractive Error and/or for Use as Bandage Lenses (Soft Corrective Contact Lenses, Extended Wear / Therapeutic Contact Lenses; Silicone Hydrogel Soft Contact Lenses, Corrective; Non-Silicone Hydrogel Soft Contact Lenses, Corrective)

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. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G1 020895 0393 Rev. 00

Report No.: 713194570

Valid from: 2021-02-05
Valid until: 2024-05-26

Date, 2021-02-05
Digitally signed by Vidiborschii Vladimir
Date: 2021.06.14 17:07:43 EEST
Reason: MoldSign Signature
Location: Moldova

Christoph Dicks
Head of Certification/Notified Body

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

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