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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 020895 0396 Rev. 06

Manufacturer:

Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099
USA

SRN Manufacturer - US-MF-000016248

Authorized Representative:

Alcon Laboratories Belgium
Lichterveld 3, 2870 Puurs-St-Amands, BELGIUM

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
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:G10 020895 0396 Rev. 06

Report No.: 713311161

Preceding Certificate No.: G10 020895 0396 Rev. 05

Valid from: 2023-12-13
Valid until: 2027-06-23

Date of Initial Issuance: 2022-07-28

[redacted]

Issue date: 2023-12-13

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No. G10 020895 0396 Rev. 06

Classification:	Class IIa
Device Group:	Q021004 - CONTACT LENSES
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q020499 - VITRECTOMY DEVICES - OTHER
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q0299 - OPHTHALMIC DEVICES - OTHER
Intended Purpose:	-
Classification:	Class IIa
Device Group:	Z121201 - OPHTALMOLOGY ASSESSMENTS AND DIAGNOSIS INSTRUMENTS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q020499 - VITRECTOMY DEVICES - OTHER
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z119099 - VARIOUS BIOIMAGING AND RADIOTHERAPY INSTRUMENTS - OTHER
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q020199 - OPHTHALMIC CUTTING DEVICES - OTHER
Intended Purpose:	./.
Classification:	Class IIb
Device Group:	Q020302 - OPHTHALMOLOGY, LIQUID FLUIDS
Intended Purpose:	Ophthalmic liquid device intended for lubrication of the ocular surface for temporary relief of dry eye symptoms and to lubricate and rewet contact lenses.

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Classification:	Class IIb
Device Group:	Q020302 - OPHTHALMOLOGY, LIQUID FLUIDS
Intended Purpose:	Intended for Contact Lenses Storing and Cleaning.

Classification:	Class IIb
Device Group:	Q020302 - OPHTHALMOLOGY, LIQUID FLUIDS
Intended Purpose:	Ophthalmic liquid device intended for lubrication of the ocular surface for temporary relief of dry eye symptoms.

Classification:	Class IIb
Device Group:	Q020302 - OPHTHALMOLOGY, LIQUID FLUIDS
Intended Purpose:	Isotonic solution for use in irrigating tissues of the eye.

Classification:	Class IIa
Device Group:	Q020303 - OPHTHALMOLOGY, VISCOELASTIC FLUIDS
Intended Purpose:	-

Classification:	Class IIa
Device Group:	Q020302 - OPHTHALMOLOGY, LIQUID FLUIDS
Intended Purpose:	-

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Handheld, sterile and single use microsurgical tools used to selectively coagulate tissue during ophthalmic surgical procedures by applying electrical energy.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for anterior capsulotomy, phacofragmentation, the creation of single plane, multi-plane and arcuate cuts/incisions in the cornea, the creation of corneal tunnels and pockets, and the creation of corneal flaps.

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Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for the removal of vitreous from the anterior chamber of the eye.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for use in cataract lens extraction surgical procedures. This system allows the surgeon to emulsify and aspirate the lens in the eye, while replacing aspirated fluid and lens material with balanced salt solution.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for use during retinal surgery to perform photocoagulation of vascular and structural abnormalities of the retina and choroid, iridotomy/iridectomy, trabeculoplasty, and other laser treatments.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for vitreous aspiration and cutting functions, as well as tissue dissection in the eye.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Is intended for ophthalmic surgeries to aid in the removal, reshaping or resurfacing of corneal tissue by photoablation.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Is intended for decentral administration and visualization of data from ophthalmic diagnostic and therapeutic devices for the planning of corneal laser surgeries.

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Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended to perform dissection of corneal tissue by sequentially applied photo disruptions in a predefined pattern.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for use during cataract surgery (emulsification, separation, and removal of cataracts, the removal of residual cortical material and lens epithelial cells, vitreous aspiration and cutting associated with anterior vitrectomy, bipolar coagulation), and for use during retinal surgery (photocoagulation of vascular and structural abnormalities of the retina and choroid, iridotomy/iridectomy, trabeculoplasty, and other treatments).

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for use during retinal surgery (photocoagulation of vascular and structural abnormalities of the retina and choroid, iridotomy/iridectomy, trabeculoplasty, and other treatments).

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended for use in the removal of cataractous lens tissue by ultrasonic (U/S) disintegration and fluidic aspiration of tissue.

Classification:	Class IIb
Device Group:	Z121202 - THERAPEUTIC AND SURGICAL OPHTHALMOLOGICAL TREATMENTS INSTRUMENTS
Intended Purpose:	Intended to be used in both anterior segment (i.e. phacoemulsification, removal of cataracts, and intraocular lens injection) and posterior segment (i.e., vitreoretinal) ophthalmic surgery in addition to the indications included with the optional laser.

The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

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Rev.	Dated	Report	Description
00	2022-07-28	713180458	-
01	2023-03-30	713255185	Supplemented: Device(s)/group of device(s) added
02	2023-06-14	713272080	Supplemented: Device(s)/group of device(s) added
03	2023-07-26	713255185	Supplemented: Device(s)/group of device(s) added
04	2023-08-18	713283573	Supplemented: Device(s)/group of device(s) added
05	2023-11-02	713294794	Supplemented: Device(s)/group of device(s) added
06	2023-12-13	713311161	-
			Supplemented: Device(s)/group of device(s) added

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