EU Quality Management Certificate

This is to certify that the company

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

SRN: DE-MF-000007732

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

For placing of devices of class IIa, IIb or III listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	263168 MDR2017Q
Certificate ID	170783041
Effective date	2023-02-16
Expiry date	2027-01-05
Frankfurt am Main,	2023-02-16

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 5.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000007732
Certificate ID: 170783041

Device categories covered by this certificate:

Device category:	**Inserter, intraocular lens**
Risk classification:	Ir
Intended purpose:	ZEISS injector system is intended for the insertion of Carl Zeiss Meditec qualified intraocular lenses in aphakic eyes.

Device category:	**Image and Report Management System**
Risk classification:	IIa
Intended purpose:	The Retina Workplace is a FORUM application intended for processing, displaying and measurement of image and optical coherence tomography data. It is also intended for generating reports that contain results from optical coherence tomography and fundus photography.

Device category:	**Patient Health Record Information System Application**
Risk classification:	IIa
Intended purpose:	The CONVIVO Pathology Workplace is designed to present confocal in vivo laser scanning images of the inner microstructure of tissue generated with Confocal Endomicroscopy systems to the pathologist. The pathologist can use CONVIVO Pathology Workplace during surgical procedures to provide fast feedback to the surgeon and to archive images for later reference.

Device category:	**Information System**
Risk classification:	IIa
Intended purpose:	CALLISTO eye is an Assistance-, Information- and Documentation system to support ophthalmic surgical procedures. Therefore, it provides interface to other devices. The system enables the visualization of the anterior and posterior segments of the eye and allows the connection and remote control of a surgical microscope using OCT Camera. It is designed for high patient throughput and can be used for teaching purposes.

Device category:	**Image and Report Management System**
Risk classification:	IIa
Intended purpose:	FORUM is a software system intended for use in storage, management, processing, and display of patient, diagnostic, video and image data and measurement from computerized diagnostic instruments or documentation systems through networks. It is intended to work with other FORUM applications. FORUM is intended for use in review of patient, diagnostic and image data and measurement by trained healthcare professionals.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000007732
Certificate ID: 170783041

Device category:	**Image and Report Management System**
Risk classification:	IIa
Intended purpose:	Glaucoma Workplace is a FORUM software application intended for the management, display, and analysis of visual field and OCT (optical coherence tomography) exam data. Glaucoma Workplace is indicated as an aid to the detection and management of visual field defects, posterior ocular structure defects, and their progression. Glaucoma Workplace is also intended for generating reports that contain results from perimetry, optical coherence tomography, and fundus photography. Glaucoma Workplace implements CIRRUS algorithms and databases for retinal nerve fiber layer thickness, ganglion cell plus inner plexiform thickness, optic nerve head measurement and Humphrey Field Analyzer algorithms and databases for visual field measurements and Guided Progression Analysis.

Device category:	**Ophthalmic laser**
Risk classification:	IIb
Intended purpose:	The VISULAS green is intended for use in photocoagulating ocular tissues in the treatment of diseases of the eye, including • Photocoagulation of the retina • Trabeculoplasty for treatment of glaucoma • Iridotomy for treatment of glaucoma

Device category:	**Ophthalmic laser**
Risk classification:	IIb
Intended purpose:	The VISUMAX® 600 and VISUMAX® 800 femtosecond lasers are indicated for use in ophthalmic surgery for the creation of lamellar and penetrating corneal incisions. Regarding the individual treatment options, they are used for the following indications: - creation of a corneal flap in patients undergoing LASIK surgery or other treatment requiring initial lamellar resection of the cornea. - refractive corrections by the creation and subsequent surgical extraction of intrastromal corneal lenticules. - penetrating or lamellar keratoplasty - surgical treatments requiring an initial corneal incision

Device category:	**Phacoemulsification system**
Risk classification:	IIb
Intended purpose:	QUATERA 700 is intended for the emulsification and removal of cataracts and anterior segment vitrectomy. The device is designed for use in anterior segment surgery. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/ aspiration, bipolar coagulation, anterior vitrectomy.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000007732
Certificate ID: 170783041

Device category:	**Posterior-chamber intraocular lens, pseudophakic**
Risk classification:	IIb implantable
Intended purpose:	This ZEISS intraocular lens is intended for implantation in the capsular bag to replace the human crystalline lens.

Device category:	**Posterior-chamber intraocular lens, pseudophakic**
Risk classification:	III implantable
Intended purpose:	This ZEISS intraocular lens is intended for implantation in the capsular bag to replace the human crystalline lens.

Device category:	**Opthalmic Examination Unit / Opthalmic intraoperative OCT System**
Risk classification:	IIa
Intended purpose:	RESCAN 700 is intended to intraoperatively acquire high resolution OCT images of anterior and posterior segments of the eye in real time. It enables the application of OCT functionality to an ophthalmic surgical microscope and provides OCT image data to an assistance system. The device includes an interface for remote control by an assistance system.

Device category:	**Ophthalmic Examination Unit**
Risk classification:	IIa
Intended purpose:	The IOLMaster 700 is to be used only for the visualization and measurement of eye structures such as axial length, anterior chamber, eye lens, retina, pupil and for the determination of corneal curvature and thickness, white-to-white distance (WTW) of the human eye and calculation of the required intraocular lens. The Option Reference Image may only be used in conjunction with the IOLMaster 700 to capture images in which sclera vessels in the vicinity of the limbus are discernible in combination with the superposition of principal meridian of corneal curvature measurement.

Device category:	**OCULAR IMPLANT INSTRUMENTS, SINGLE-USE**
Risk classification:	IIa
Intended purpose:	The BLUEMIXS 180 injector is intended for the injection of Carl Zeiss Meditec's preloaded micro-incision cataract surgery (MICS) intraocular lenses (IOLs). The injector is made of medical grade plastic and medical grade stainless steel. It consists of two main parts: the plunger and the body. It allows the insertion of an IOL that comes prepacked in a compatible cartridge (separate product). Together, the injector and the cartridge constitute an injection system used for the implantation of compatible foldable acrylate intraocular lenses in the capsular bag of the eye, after extraction of the natural crystalline lens.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000007732
Certificate ID: 170783041

Device category:	**Ophthalmic laser**
Risk classification:	IIb
Intended purpose:	The VISULAS yag is intended for use in photodisrupting ocular tissues in the treatment of diseases of the eye, including • Posterior capsulotomy • Iridotomy • Membranectomy

Device category:	**Ophthalmic laser**
Risk classification:	IIb
Intended purpose:	The VISULAS combi is intended for use in photocoagulating and photodisrupting ocular tissues in the treatment of diseases of the eye, including • Photocoagulation of the retina • Trabeculoplasty • Iridotomy • Posterior capsulotomy • Membranectomy The VISULAS combi is intended for use in selective laser trabeculoplasty (SLT).

Device category:	**Software for Ophthamology Treatment**
Risk classification:	IIb
Intended purpose:	VISULYZE is a calculation tool intended to assist the ophthalmic healthcare professional with data collection and analysis of their laser vision correction outcomes with ZEISS refractive lasers. The tool will then propose Users nomograms as an output, based on the data selected. The proposed Users nomogram can be used as an input for the ZEISS refractive lasers.

Device category:	**Software for Ophthamology Treatment**
Risk classification:	IIb
Intended purpose:	The Refractive Workplace (REFWP) is a software that accepts data from a data source (e.g. FORUM) intended to support an ophthalmic healthcare professional in assessing suitable treatment options for potential Laser Vision Correction (LVC) patients. It supports the treatment planning for the ZEISS refractive lasers. The application also uses diagnostic data for specific ZEISS refractive laser procedure types.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000007732
Certificate ID: 170783041

Device category:	**Ophthalmic lasers**
Risk classification:	IIb
Intended purpose:	The primary intended use is to alter the form of the cornea by removing corneal tissue to achieve an improvement in visual acuity. The MEL 90 is designed for refractive corneal surgery using LASIK (LAser (-assisted) in SItu Keratomileusis) and PRK (PhotoRefractive Keratectomy) treatment techniques. It can also be used to carry out superficial therapeutic PTK (PhotoTherapeutic Keratectomy) treatment. LASIK and PRK treatments can be used to correct myopia within a range of 0 D to -12 D plus up to -3 D astigmatism and hyperopia within a range of 0 D to +3 D including +3 D astigmatism.

Device category:	**Information System**
Risk classification:	lla
Intended purpose:	EQ Workplace is a software intended to support a user in selecting intraocular lenses by calculation of intraocular lens power and predicted residual refraction. Furthermore, it is intended to support a user in cataract and refractive surgery planning and post-surgical data management.

Device category:	**Fluorescence Option**
Risk classification:	lla
Intended purpose:	INFRARED 800 with FLOW 800 Option used during fluorescence guided surgery aids in viewing the visual assessment of intraoperative blood flow as well as vessel patency in surgical procedures in neurosurgery, plastic and reconstructive procedures and coronary artery bypass graft surgery.

Device category:	**Accessory to Phacoemulsification system**
Risk classification:	lla
Intended purpose:	This single use device is an accessory for Zeiss phaco systems. It has been designed to emulsify and aspirate the eye lens during human cataract surgery.

Device category:	**STED ATLAS 500**
Risk classification:	lla
Intended purpose:	ZEISS ATLAS 500 is a medical device used to perform corneal topography and capture date to assist ophthalmic practitioners with the assessment of lacrimal dysfunctions. The device has been designed to capture and evaluate images of the anterior eye segment in the ophthalmic workflow.

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000007732
Certificate ID: 170783041

Examinations and tests performed:
263168_A208622MEDAuditReportMDRStageII2021-06-18 dated 2021-08-23

Further conditions for or limitations to the validity of the certificate:
The manufacturer's quality management system is subject to periodic surveillance in accordance with Annex IX, Chapter 1, Section 3.
In the case of reusable surgical instruments, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects related to reuse, in particular cleaning, disinfection, sterilization, maintenance and functional testing, as well as the related instructions for use.
For placing class IIb implantable medical devices listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2022-03-24	170779718	Addition FORUM, RESCAN 700, IOLMASTER 700, CALLISTO eye Software and CONVIVO Pathology Workplace
02	2022-05-27	170780075	Addition of BLUEMIXS 180, VISULAS yag & VISULAS combi
03	2022-09-01	170780821	Addition VISULYZE, Refractive Workplace, MEL 90, EQ Workplace and INFRARED 800 with FLOW 800 Option
04	2022-11-11	170781352	Addition of Accessory to Phacoemulsification system and STED ATLAS 500