



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Imaging devices utilising non-ionizing radiation (MD 1202), Devices utilising ionizing radiation (MD 1401), Devices utilising non-ionizing radiation (MD 1402), Active surgical devices (MD 1104), Active ophthalmologic devices (MD 1105), Software (MD 1111), Non-active functional implants (MD 0203), Non-active medical devices with measuring function (MD 0104), Non-active ophthalmologic devices (MD 0105), Non-active instruments (MD 0106), Non-active device for disinfecting, cleaning and rinsing (MD 0108), as listed in the annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	263168 MR2
Certificate unique ID	170774133
Effective date	2021-03-02
Expiry date	2024-05-26
Frankfurt am Main	2021-03-02

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 263168 MR2
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Effective date: 2021-03-02

Carl Zeiss Meditec AG

Goeschitzer Strasse 51 - 52
07745 Jena
Germany

Device Family / Devices	Category Code	Class
Ophthalmic Examination Unit	MD 1105	Ila
Ophthalmic Lasers and accessories	MD 1105 MD 0105	Ila / IIb
Applanation Tonometer	MD 0104	Im
Posterior-Chamber Intraocular Lens (pseudophakic)		
AT LARA 829MP, AT LARA toric 929M, AT LARA toric 929MP, AT LISA 801, AT LISA 809M, AT LISA 809MP, AT LISA 809MV, AT LISA tri 839MP, AT LISA tri toric 939M, AT LISA tri toric 939MP, AT LISA tri toric 949M, AT LISA tri toric 949MP, AT LISA toric 909M, AT LISA toric 909MP, AT TORBI 709M, AT TORBI 709MP, AT TORBI 719M, AT TORBI 719MP, CT 27SF, CT 37A, CT 47LC, CT 47S, CT SPHERIS 204, CT SPHERIS 209M, CT ASPHINA 404, CT ASPHINA 409M, CT ASPHINA 409MP, CT ASPHINA 409MV, CT ASPHINA 509M, CT ASPHINA 509MP	MD 0203	IIb
CT LUCIA 202, CT LUCIA 602	MD 0203	IIb
CT LUCIA 601P, CT LUCIA 601PY, CT LUCIA 201P, CT LUCIA 611P, CT LUCIA 611PY, CT LUCIA 211P, CT LUCIA 211PY, CT LUCIA 621P, CT LUCIA 621PY, CT LUCIA 221P	MD 0203	III
AT ELANA 841P	MD 0203	III
Anterior-Chamber Intraocular Lens (pseudophakic)		
CT 13A	MD 0203	IIb
Aqueous/Vitreous Humour Replacement Medium	MD 0105	IIb
Z-HYALON, Z-HYALON plus	MD 0105	III
Surgical/Medical Procedure Irrigation Fluid	MD 0108	Ila
Inserters, Intraocular Lens	MD 0105	Ila



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Carl Zeiss Meditec AG

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Device Family / Devices	Category Code	Class
Radiosurgery Treatment Systems	MD 0104 MD 0106 MD 0106 MD 1401	Im Is IIa IIb
INTRABEAM Needle Applicator (accessory to the Radiosurgery Treatment Systems) INTRABEAM Spherical Applicator (accessory to the Radiosurgery Treatment Systems)	MD 0106	III
Surgical Microscopes incl. Fluorescence Option	MD 1104 MD 1402	IIa IIa
Patient Health Record Information System Application Software	MD 1111	IIa
Operating Room Audio Visual Data/Device Management System	MD 1111	IIa
Intraocular Lens web-based Calculator Software	MD 1111	IIa
Phacoemulsification Systems and accessories	MD 0106 MD 0105 MD 1105	Is IIa IIb
Medical Equipment Drape, single-use, sterile	MD 0106	Is
Endoscopes and Endoscopic Visualization Systems		
QEVO	MD 1202	III
Confocal Endomicroscopy	MD 1202	IIa
Sterile Sheath for CONVIVO	MD 0106	III



CERTIFICATE



This is to certify that the company

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope:

Design, manufacture, distribution, installation and service of therapeutic, surgical and diagnostic devices as well as accessories for ophthalmology and surgery – especially ophthalmic lasers, slit lamps, tonometer, optical products for surgery, acrylic intraocular lenses, surgical microscopes, systems for radiotherapy and phacoemulsification, examination devices, endoscopes and endoscopic visualization systems including software for programmable medical devices (systems) and self-contained software solutions for medical data and image management systems to be used within clinical settings.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	263168 MP2016
Certificate unique ID	170715381
Effective date	2019-03-08
Expiry date	2022-03-07
Frankfurt am Main	2019-03-08



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

Dr. Thomas Feldmann
Head of Certification Body



Annex to certificate

Certificate registration No.: 263168 MP2016

Certificate unique ID: 170715381

Effective date: 2019-03-08

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

Location

Scope

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

Design, manufacture, distribution, installation and service of therapeutic and diagnostic devices as well as accessories for ophthalmology and surgery – especially ophthalmic lasers, examination devices, slit lamps, tonometer, software.

Carl Zeiss Meditec AG

Carl-Zeiss-Promenade 10
07745 Jena
Germany

Design, manufacture, distribution, installation and service of therapeutic and diagnostic devices as well as accessories for ophthalmology and surgery – especially ophthalmic lasers, examination devices, slit lamps, tonometer, software.

Carl Zeiss Meditec AG

Max-Dohrn-Strasse 8 - 10
10589 Berlin
Germany

Design, manufacture and distribution of therapeutic and diagnostic devices for ophthalmology and surgery – especially acrylic intraocular lenses.

Carl Zeiss Meditec AG

Rudolf-Eber-Strasse 11
73447 Oberkochen
Germany

Design, manufacture, distribution, installation and service of therapeutic, surgical and diagnostic devices as well as accessories for ophthalmology and surgery – especially examination devices, endoscopes and endoscopic visualization systems, optical products for surgery, surgical microscopes, systems for radiotherapy and phacoemulsification, software.

Carl Zeiss Meditec AG

Kistlerhofstrasse 75
81379 München
Germany

Design and development of software for programmable medical devices (systems) and self-contained software solutions for medical data management systems to be used within clinical settings; assistance with installation, application and servicing.



Annex to certificate

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Certificate unique ID: 170715381

Effective date: 2019-03-08

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

Location

Scope

Carl Zeiss Meditec SAS
27, Avenue Paul Langevin
17180 Périgny
France

Design, manufacture and distribution of implantable or not implantable medical devices for ophthalmological area.
Manufacture as subcontractor of intraocular lenses and phaco cassettes.

**Carl Zeiss India (Bangalore) Pvt. Ltd.
CARIn Division**
Plot No. 3 Jigani Link Road
Bommasandra Industrial Area
Bangalore 560 099
India

Design, development and manufacture of medical software.

Carl Zeiss Meditec Production LLC
1040 South Vintage Ave., Bldg. A
Ontario, CA, 91761
United States of America

Design and Development, Manufacture and Distribution of Intraocular Lenses, Raw Materials for Intraocular Lenses and Injection Systems for Intraocular Lenses.



EC Declaration of Conformity

in accordance with EC Directive 93/42/EEC on Medical Devices

Manufacturer Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany

We Carl Zeiss Meditec AG herewith declare with sole responsibility that the following Medical Device meets the Requirements of the European Directive 93/42/EEC. The device is provided with CE Marking with the number of the Notified Body.

Product identification: *Phacoemulsification System*

Medical Device Trade Name: *VISALIS S500
VISALIS V500*

Models/Reference: *640420
640430*

Accessories *CALLISTO eye and see Backside*

Medical Device Class:
MDD 93/42/EEC *Class IIb*

Conformity Assessment Procedure : *Annex II of MDD 93/42/EEC*

Scope of Application: This Declaration of Conformity is valid for all products manufactured until 2024-05-26.

UMDNS code: *17-596*

GMDN code: *45072*

Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt - notified under 0297.

Any Modification to the product not authorized by Carl Zeiss Meditec AG will invalidate this Declaration.


i. V. Alexandre Mariet
Vice President Competence Center
Surgical Devices & Systems


i.V. Dr. Hans-Joachim Miesner
Head of Regulatory Affairs and Clinical Affairs Active
Devices



Catalogue Number	Accessory Name
I/A Tubing	
303060-0204-000	I/A TUBING CASSETTE QUICKSET
303060-0208-000	CATARACT ADVANCED IRRIGATION TUBING
303060-0210-000	RETINA ADVANCED IRRIGATION TUBING
Accessories for Phacoemulsification – U/S Handpiece	
303060-0001-000	ULITE PHACO HANDPIECE
Accessories for Phacoemulsification – Phaco Sets	
303060-1020-000	PHACO SET PLUS 20G,STRAIGHT,15°
303060-1021-000	PHACO SET PLUS 20G,STRAIGHT,30°
303060-1022-000	PHACO SET PLUS 20G,FLARED,30°
303060-1023-000	PHACO SET PLUS 21G,BICONICAL,15°
303060-1024-000	PHACO SET PLUS 21G,BICONICAL,30°
303060-1025-000	PHACO SET PLUS 21G,FLARED,30°
303060-1026-000	PHACO SET PLUS 22G,BICONICAL,15°
303060-1027-000	PHACO SET PLUS 22G,BICONICAL,30°
303060-1028-000	PHACO SET PLUS 22G,FLARED,30°
303060-1030-000	SLEEVE, TEST CHAMBER SET PLUS 20G
303060-1031-000	SLEEVE, TEST CHAMBER SET PLUS 21G
303060-1032-000	SLEEVE, TEST CHAMBER SET PLUS 22G
Accessories for Phacoemulsification – Tips	
303060-0050-000	19G PHACO TIP,15°
303060-0051-000	19G PHACO TIP,30°
303060-0052-000	19G PHACO TIP,45°
303060-0053-000	20G PHACO TIP,BICONICAL
303060-0054-000	20G PHACO TIP,15°
303060-0055-000	20G PHACO TIP,30°
303060-0056-000	20G PHACO TIP,45°
303060-0057-000	22G PHACO TIP,30°,SLEEVELESS BIMANUAL
303060-0058-000	22G PROGR. PHACO TIP,SLEEVELESS BIMANUAL
303060-0059-000	21G PHACO TIP,BICONICAL,15°
303060-0060-000	21G PHACO TIP,BICONICAL,30°
303060-0062-000	20G PHACO TIP,20°,ANGLED
303060-0063-000	22G PHACO TIP,BICONICAL
303060-0064-000	PARS PLANA PHACO TIP
303060-0065-000	22G PHACO TIP,BICONICAL,30°
303060-0068-000	20G PHACO TIP, 30° FLARED *
303060-0069-000	21G PHACO TIP, 30° FLARED *
303060-0070-000	22G PHACO TIP, 30° FLARED*
* Product of Medcel	
Accessories for Phacoemulsification – Sleeves	
303060-0100-000	19G SILICONE SLEEVE (GREY) 2.9-3.2MM
303060-0101-000	20G SILICONE SLEEVE (BLUE) 2.6-2.8MM
303060-0102-000	21G SILICONE SLEEVE (YELLOW) 2.2-2.5MM
303060-0103-000	22G SILICONE SLEEVE (GREEN) 1.7-2.1MM
Accessories for Phacoemulsification - Additional Accessories	
303060-0121-000	PHACO TIP WRENCH
303060-0202-000	TEST CHAMBER



Catalogue Number	Accessory Name
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Accessories for I/A - Bimanual Technique	
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303060-0155-000	IRRIGATION HANDPIECE, BIMANUAL
303060-0156-000	ASPIRATION HANDPIECE, BIMANUAL
303060-0165-000	IRR & ASP HANDPIECES BIMANUAL
303060-0166-000	IRR & ASP HANDPIECES BIMANUAL FRONT

Accessories for I/A - Coaxial Technique	
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303060-0140-000	I/A HANDPIECE, COAXIAL, REUSABLE
303060-0141-000	I/A HANDPIECE, 20G STRAIGHT
303060-0142-000	I/A HANDPIECE, 20G ANGLED 45°
303060-0143-000	I/A HANDPIECE, 21G ANGLED 45°
303060-0144-000	I/A HANDPIECE, 22G ANGLED 45°
303060-0145-000	I/A HANDPIECE, 22G CURVED
303060-0146-000	I/A HANDPIECE, 21G CURVED
303060-0150-000	I/A CANNULA, METAL SLEEVE, STRAIGHT, Ø1.6MM
303060-0151-000	I/A CANNULA, METAL SLEEVE, ANGLED, Ø1.6MM
303060-0152-000	I/A CANNULA, METAL SLEEVE, CURVED, Ø1.6MM
303060-0153-000	I/A CANNULA, MET. SLEEVE, 12 O'CLOCK, Ø1.6MM
303060-0154-000	I/A CANNULA, METAL SLEEVE, 90°, Ø1.6MM
303060-0157-000	19G I/A CANNULA, SILICONE SLEEVE, STRAIGHT
303060-0158-000	19G I/A CANNULA, SILICONE SLEEVE, ANGLED
303060-0159-000	20G I/A CANNULA, SILICONE SLEEVE, STRAIGHT
303060-0160-000	20G I/A CANNULA, SILICONE SLEEVE, ANGLED
303060-0161-000	21G I/A CANNULA, SILICONE SLEEVE, STRAIGHT
303060-0162-000	21G I/A CANNULA, SILICONE SLEEVE, ANGLED
303060-0163-000	22G I/A CANNULA, SILICONE SLEEVE, STRAIGHT
303060-0164-000	22G I/A CANNULA, SILICONE SLEEVE, ANGLED

Accessories for Diathermy	
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303060-0250-000	DIATHERMY BIPOLAR CABLE
303060-0251-000	DIATHERMY FORCEPS
303060-0252-000	DIATHERMY PENCIL ERASER

Accessories for Anterior Vitrectomy	
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303060-0301-000	20G A-VIT PROBE WITH SLEEVE
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Accessories for Vitreoretinal Surgeries - Trocar and Infusion Systems	
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303060-0503-000	20G SCLERAL INFUSION CANNULA
303060-0414-000	RETILOCK®— 23G NON VALVED SELF-RETAINING TROCAR *
303060-0415-000	RETILOCK® 23G VALVED SELF-RETAINING TROCAR *
303060-0416-000	RETILOCK® 25G NON VALVED SELF-RETAINING TROCAR *
303060-0417-000	RETILOCK® 25G VALVED SELF-RETAINING TROCAR *
303060-0423-000	23 Gauge BB Vitreous Cutter, RZ, w/ 72" Anterior Tubing Set, Sterile, Single Use **

* RETILOCK® is a registered trademark of FCI S.A.S

** Product of MIDLabs



Catalogue Number	Accessory Name
Accessories for Vitreoretinal Surgeries - Posterior Vitrectomy	
303060-0403-000	20G POSTERIOR VITRECTOMY PROBE
303060-0407-000	23G POSTERIOR VITRECTOMY PROBE
303060-0408-000	25G POSTERIOR VITRECTOMY PROBE
Accessories for Vitreoretinal Surgeries - Endoillumination	
303060-0600-000	20G ENDO-ILLUMINATION PROBE
303060-0601-000	20G WIDE-ANGLE ENDO-ILLUMINATION PROBE
303060-0602-000	20G ENDO-ILLUMINATION PROBE MULTIPOINT
303060-0603-000	20G WIDE-ANGLE ENDO-ILLUMIN. MULTIPOINT
303060-0604-000	23G ENDO-ILLUMINATION PROBE MULTIPOINT
303060-0605-000	23G WIDE-ANGLE ENDO-ILLUMIN. MULTIPOINT
303060-0606-000	25G ENDO-ILLUMINATION PROBE MULTIPOINT
Accessories for Vitreoretinal Surgeries - Injection and Removal Systems	
303060-0505-000	TWO WAY STOPCOCK
303060-0506-000	ADAPTER AIR / CONTROLLED IRRIGATION
303060-0507-000	VISCOUS FLUID REMOVAL KIT
303060-0508-000	AIR INJECTION TUBE WITH FILTER
303060-0509-000	SILICONE OIL INJECTION TUBE
Accessories for Vitreoretinal Surgeries - Endodiathermy	
303060-0262-000	20G ENDODIATHERMY PROBE
303060-0263-000	23G ENDODIATHERMY PROBE
303060-0264-000	25G ENDODIATHERMY PROBE
Drapes	
303060-0352-000	SCREEN DRAPE VISALIS 500
303060-0353-000	REMOTE CONTROL COVER VISALIS
303060-0354-000	TRAY COVER VISALIS 500
Miscellaneous Accessories	
303060-0350-000	STERILISATION TRAY