



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), Ethylene oxide gas sterilization (MDS 7006-1) 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	170758945
Effective date	2019-11-29
Expiry date	2024-05-26
Frankfurt am Main	2019-11-29

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
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Device Family / Devices	Category Code	Class
Ophthalmic Examination Unit	MD 1105	IIa
Ophthalmic Lasers and accessories	MD 1105 MDS 7006-1	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
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	IIa
Inserters, Intraocular Lens	MD 0105	IIa
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



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Device Family / Devices	Category Code	Class
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