



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	170671154
Effective date	2017-01-25
Expiry date	2021-11-29
Frankfurt am Main	2017-01-25

DQS Medizinprodukte GmbH

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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	Device	Class
Ophthalmic examination unit	IOLMaster and accessories incl. models IOLMaster, IOLMaster 500, IOLMaster 700 (UMDNS 18-014) (GMDN 48064) VISUCAM and accessories, incl. models VISUCAM ^{PRO NM} , VISUCAM ^{NM/FA} VISUCAM 200, VISUCAM 500 VISUCAM 224, VISUCAM 524 (UMDNS 12-815) (GMDN 10551) WASCA Analyzer and accessories (UMDNS 13-313) (GMDN 45193) CIRRUS photo and accessories, incl. models CIRRUS photo 600, CIRRUS photo 800 (UMDNS 12-815 + 18-191) (GMDN 10551 + 58850) VISUREF 100 (UMDNS 12-811 + 13-313) (GMDN 12811 + 36386) RESCAN 700 (UMDNS 12-815) (GMDN 58850) VISUPLAN 500 (UMDNS 16-809) (GMDN 16-809) VISUPAC systems and accessories (UMDNS 12-815) (GMDN 52748)	Ila
Ophthalmic Lasers and accessories	VISULAS YAG III and accessories, incl. Option Combi (UMDNS 16-947) (GMDN 16947) VISULAS 532s with VISULINK 532/U and accessories, incl. Option VISULAS 532s VITE (UMDNS 17-446) (GMDN 44731) VISULAS 690plus with VISULINK PDT/U and accessories (UMDNS 12-299) (GMDN 44731) MEL 80 with option CRS-Master and accessories (UMDNS 17-702) (GMDN 17702) MEL 90 with option CRS-Master and accessories (UMDNS 17-702) (GMDN 17702) VisuMax with Treatment-Pack and accessories (UMDNS 17-446) (GMDN 58129) VISULAS Trion and accessories, incl. option VISULAS Trion Combi, VISULAS Trion VITE (UMDNS 17-446) (GMDN 16947 + 44731) Endoprobe (as accessory) (UMDNS 15-328) (GMDN 17193)	Ilb
Applanationtonometer	AT 020 and AT 030 (UMDNS 16-809) (GMDN 32721)	Im



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Posterior-chamber intraocular lens (pseudophakic)	CT 47LC, CT 51LC, CT ASPHINA 409M, CT ASPHINA 409MP, CT ASPHINA 404, CT 37A, CT 35A, CT ASPHINA 509M, CT ASPHINA 509MP, AT LARA 829MP, AT LISA 801, AT LISA 802, 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 toric 909M, AT LISA toric 909MP, AT LISA toric 909MV, CT 47S, CT 53N, CT SPHERIS 204, CT SPHERIS 209M, CT Xtreme D, AT TORBI 709M, AT TORBI 709MP, CT 59RET, CT ASPHINA 409MV, CT 47LCV, CT ASPHINA 404V, CT 27SF, CT NOVA 609MP (UMDNS 16-071) (GMDN 35658)	IIb
	CT LUCIA 202 CT LUCIA 602 (UMDNS 16-071) (GMDN 35658)	IIb
	CT LUCIA 601P, CT LUCIA 601PY CT LUCIA 201P, CT LUCIA 201PY CT LUCIA 611P, CT: LUCIA 611PY CT LUCIA 211P, CT LUCIA 211PY CT LUCIA 621 P, CT LUCIA 621PY CT LUCIA 621PY TM CT LUCIA 221P (UMDNS 16-071) (GMDN 35658)	III
Posterior-chamber intraocular lens (phakic)	Epi.Lens (UMDNS 16-071) (GMDN 47413)	IIb
Anterior-chamber intraocular lens (pseudophakic)	CT 13A, (UMDNS 16-068) (GMDN 35655)	IIb
Aqueous/vitreous humour replacement medium	RT SIL-OL 5000, RT SIL-OL 1000 (UMDNS 16-844) (GMDN 35907)	IIb
	Z-HYALON, Z-HYALON plus (UMDNS n/a) (GMDN 35907)	III
	Z-CELCOAT (UMDNS n/a) (GMDN 35907)	IIb
	RT DECALIN, RT OCTA (UMDNS n/a) (GMDN 35907)	IIb
Surgical/medical procedure irrigation fluid	PURI CLEAR (UMDNS PURI CLEAR, 16-844) (GMDN 37207)	IIb

This annex is only valid in connection with the above-mentioned certificate.



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Inserters, intraocular lens	AT.Smart Cartridge Set, ACM 2 Cartridge Set (UMDNS 17-544) (GMDN 47726)	IIa
Radiosurgery Treatment Systems	INTRABEAM PRS 500 (UMDNS-Nr. 16-973) (GMDN 59677) INTRABEAM 600 (UMDNS-Nr. 16-973) (GMDN 59677)	IIb
	INTRABEAM Needle Applicator (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59685) INTRABEAM Spherical Applicator (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59681)	III
	INTRABEAM Cylinder V Applicator Set (accessory to the Radiosurgery Treatment Systems) (UMDNS 16-397) (GMDN 59684) INTRABEAM Flat Applicator Set (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59681) INTRABEAM Surface Applicator Set (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59683) INTRABEAM Balloon Applicator Set (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59686) INTRABEAM IORT Balloon Applicator Set (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59686) INTRABEAM CBG Set (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59686) INTRABEAM Probe Guard Set (accessory to the Radiosurgery Treatment Systems) (UMDNS 15-689) (GMDN 59687)	IIa
	INTRABEAM Drape (UMDNS 15-775) (GMDN 45021)	Is
	INTRABEAM Water Phantom (Measurement equipment) (UMDNS-Nr. 16-607) (GMDN 40631)	Im



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Surgical Microscopes	OPMI Pentero with Option BLUE 400 and FLOW 800 and INFRARED 800 (UMDNS-Nr. 12-539) (GMDN 41895) OPMI PENTERO 800 with Option BLUE 400, YELLOW 560, INFRARED 800 and FLOW 800 (UMDNS-Nr. 12-539) (GMDN 41895) OPMI PENTERO 900 with Option BLUE 400, YELLOW 560, INFRARED 800 and FLOW 800 (UMDNS-Nr. 12-539) (GMDN 41895)	Ila
Image and Report Management System	FORUM Glaucoma Workplace Retina Workplace (UMDNS-Nr. 17-222) (GMDN 44106)	Ila
Information System	CALLISTO eye (UMDNS 17-222) (GMDN 58117)	Ila
Calculation Software	Z CALC (UMDNS 17-222) (GMDN 52847)	Ila
Phacoemulsification Systems	Visalis 100 incl. accessories VISALIS S500 incl. accessories VISALIS V500 incl. accessories (UMDNS-Nr. 17-596) (GMDN 45072)	Ilb
Drapes	OPMI Drapes sterile (UMDNS 15-775) (GMDN 45021) DRAPES sterile (UMDNS 15-775) (GMDN 45021) Drapes (UMDNS 15-775) (GMDN 45021) Vision Guard Replacement Lenses (UMDNS 15-775) (GMDN 45021)	Is
Endoscopes and endoscopic visualization systems	QEVO (UMDNS 14-364) (GMDN 36904)	III