



EC-CERTIFICATE

(Full quality assurance system)

DQS Medizinprodukte GmbH

hereby certifies 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.

An audit, documented in a report, performed by DQS, has verified that this quality assurance system fulfils the requirements of

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

with respect to the following medical devices:

Medical Devices Medical Devices as listed in the annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body 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. In case of class Is devices the certificate is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. In case of class Im devices the certificate is restricted to the aspects of manufacture concerned with the conformity of the products with metrological requirements.

Certificate registration No.	263168 MR2
Certificate unique ID	170532443
Effective date	2011-10-06
Expiry date	2013-11-29
Frankfurt am Main	2011-10-06

Frank Graichen
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Head of Certification Body

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



Annex to Certificate
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Device family	Device	Class
Ophthalmic examination unit	IOLMaster and accessories incl. model IOLMaster 500 (UMDNS 18-014) (GMDN n/a) VISUCAM and accessories, incl. models VISUCAM ^{PRO NM} , VISUCAM ^{NM/FA} VISUCAM 200, VISUCAM 500 (UMDNS 12-815) (GMDN n/a) WASCA Analyzer and accessories (UMDNS 13-313) (GMDN n/a)	Ila
Ophthalmic Lasers and accessories	VISULAS YAG III and accessories, incl. Option Combi (UMDNS 16-947) (GMDN n/a) VISULAS 532s with VISULINK 532/U and accessories, incl. Option VISULAS 532s VITE (UMDNS 17-446) (GMDN n/a) VISULAS 690 ^{plus} with VISULINK PDT/U and accessories (UMDNS 12-299) (GMDN n/a) MEL 80 with option CRS-Master and accessories (UMDNS 17-702) (GMDN n/a) VisuMax with Treatment-Pack and accessories (UMDNS 17-446) (GMDN n/a) VISULAS Trion and accessories, incl. option VISULAS Trion Combi, VISULAS Trion VITE (UMDNS 17-446) (GMDN n/a) Endoprobe (as accessory) (UMDNS 15-328) (GMDN n/a)	Ilb
Applanationtonometer	AT 020 and AT 030 (UMDNS 16-809) (GMDN n/a)	Im
Posterior-chamber intraocular lens (pseudophakic)	CT 47LC, CT 51LC, CT ASPHINA 409M, CT ASPHINA 404, CT ASPHINA 404P, CT 37A, CT 35A, CT ASPHINA 509M, AT LISA 801, AT LISA 802, AT LISA 809M, AT LISA 809MP, AT LISA 809MV, AT LISA tri 839MP, AT LISA toric 909M, AT LISA toric 909MP, AT LISA toric 909MV CT 47S, CT 53N, CT SPHERIS 204, CT SPHERIS 204P, 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 AR Acri.Lyc 47LC, Acri.Lyc 51LC, Acri.Smart 46LC, Acri.Lyc 44LC, Acri.Lyc 37A, Acri.Lyc 35A, Acri.Lyc 36A, Acri.Lisa 376D, Acri.Lisa 536D, *Acri.Lisa 366D, Acri.Lisa toric 466TD, Acri.Lyc 47S, Acri.Lyc 53N, Acri.Lyc 44S, Acri.Smart 46S, Acri.Lyc 164Xtermed, Acri.Comfort 646TLC, Acri.Lyc 59RET, Acri.Smart 46YLC, Acri.Lyc 47YLC, Acri.Lyc 44YLC Acri.Lens 27SF, Acri.Lens AR (GMDN P 35658), (UMDNS 16-071)	Ilb



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Posterior-chamber intraocular lens (phakic)	Epi.Lens (GMDN P 47413), (UMDNS 16-071)	IIb
Anterior-chamber intraocular lens (pseudophakic)	CT 13A, Clemente Optifit 13A (GMDN P 35655), (UMDNS 16-068)	IIb
Capsular tension ring	TENSIOBAG blue 10, TENSIOBAG blue 11, TENSIOBAG blue 12 Acri.Ring BR10, Acri.Ring BR11, Acri.Ring BR12 (GMDN P 42839), (UMDNS 11-908)	IIb
Intracorneal ring segment	CR KERA 0,35, CR KERA 0,45 Acri.Kera (GMDN P 46903), (UMDNS 18-103)	IIb
Aqueous/vitreous humour replacement medium	RT SIL-OL 5000, RT SIL-OL 1000 Acri.Sil-ol 5000, Acri.Sil-ol 1000 (GMDN P 35907), (UMDNS 16-844)	IIb
	Z-HYALON, Z-HYALON plus Acri.Hylon, Acri.Hylon plus (GMDN P 35907), (UMDNS n/a)	III
	Z-CELCOAT Acri.Viscose (GMDN P 35907), (UMDNS n/a)	IIb
Surgical/medical procedure irrigation fluid	PURI CLEAR, PURI PROTECT PURI SOL / Acri.Pur, Acri.ProTect (GMDN P 37207), (UMDNS PURI PROTECT, Acri.ProTect n/a), (UMDNS PURI CLEAR, PURI SOL, Acri.Pur 16-844)	IIb
Retinal tamponade medium, intraoperative	RT DECALIN, RT OCTA Acri.Deca, Acri.Octa (GMDN P 45283), (UMDNS n/a)	IIb
Inserters, intraocular lens	AT.Smart Cartridge Set, ACM 2 Cartridge Set Acri.Smart Cartridge, ACM 2, (GMDN n/a), (UMDNS 17-544)	IIa
Adapter of retinal tamponade medium, intraoperative	Vial.Adapt Acri.Vial.Adapt (GMDN n/a), (UMDNS n/a)	Is



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Device family	Device	Class
Tube Set of aqueous/vitreous humour replacement medium	Tube Set (GMDN n/a), (UMDNS n/a)	IIa
Radiosurgery Treatment Systems	PRS400 and PRS500 (GMDN CT109 / UMDNS-Nr. 16-973)	IIb
	INTRABEAM Needle Applicator (accessory to the Radiosurgery Treatment Systems) INTRABEAM Spherical Applicator (accessory to the Radiosurgery Treatment Systems) INTRABEAM Radiation Shields (accessory to the Radiosurgery Treatment Systems) (GMDN CT109 / UMDNS-Nr. 14-490)	III
	INTRABEAM Gyn Applicator Set, 3,5cm (accessory to the Radiosurgery Treatment Systems) INTRABEAM Flat Applicator Set, 5,0cm (accessory to the Radiosurgery Treatment Systems)	IIa
Surgical Microscopes	OPMI Pentero with Option Blue 400 and Infrared 800 and Flow 800 (GMDN CT127 / UMDNS-Nr. 12-539)	IIa
	OPMI Pentero C with Option Blue 400 and Infrared 800 and Flow 800 (GMDN CT127 / UMDNS-Nr. 12-539)	
	OPMI PENTERO 900 with Option Blue 400, Yellow 560, Infrared 800 and Flow 800 (GMDN CT127 / UMDNS-Nr. 12-538)	
Image and Report Management System	FORUM (GMDN CT223 / UMDNS-Nr. 17-222)	IIa
Phacoemulsification Systems	VISALIS 100 incl. accessories VISALIS S500 incl. accessories VISALIS V500 incl. accessories (GMDN CT230 / UMDNS-Nr. 17-596)	IIb