



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 selfcontained 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 170775820

Effective date 2021-11-19

Expiry date 2024-11-18

Frankfurt am Main 2021-11-19

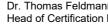


DQS Medizinprodukte GmbH

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

Sigrid Uhlemann Managing Director

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Head of Certification Body





Annex to certificate

Certificate registration No.: 263168 MP2016

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Effective date: 2021-11-19

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52 07745 Jena Germany

Location

462969

Carl Zeiss Meditec AG Goeschwitzer Strasse 51 - 52

07745 Jena Germany

Scope

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.

462684

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.

494570

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 and raw materials for intraocular lenses.

509545

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.







Annex to certificate

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Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52 07745 Jena Germany

Location

494569

Carl Zeiss Meditec AG

Kistlerhofstrasse 75 81379 München Germany

Scope

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.

393678

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.

510586

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.

516728

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.

548680

Carl Zeiss Meditec Guangzhou Ltd

No.1389 Jiufo Xilu 510555 Guangzhou China Manufacture and distribution of intraocular lenses.

