



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

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 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.