



# 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. 2 Certificate unique ID Effective date 2 Expiry date 2 Frankfurt am Main 2

263168 MP2016 170715381 2019-03-08 2022-03-07 2019-03-08

#### **DQS Medizinprodukte GmbH**

Mb lund

Sigrid Uhlemann Managing Director August-Schanz-Straße 21, 60433 Frankfurt am Main, Tel. +49 (0) 69 95427-300, <u>medical.devices@dqs-med.de</u>



Dr. Thomas Feldmann Head of Certification Body

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### 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

**Carl Zeiss Meditec AG** Goeschwitzer Strasse 51 - 52 07745 Jena Germany

Carl Zeiss Meditec AG Carl-Zeiss-Promenade 10 07745 Jena Germany

Carl Zeiss Meditec AG Max-Dohrn-Strasse 8 - 10 10589 Berlin Germany

Carl Zeiss Meditec AG Rudolf-Eber-Strasse 11 73447 Oberkochen 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.

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.

Design, manufacture and distribution of therapeutic and diagnostic devices for ophthalmology and surgery – especially acrylic intraocular lenses.

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.







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# **Carl Zeiss Meditec AG**

Goeschwitzer Strasse 51 - 52 07745 Jena Germany

Location

**Carl Zeiss Meditec SAS** 27, Avenue Paul Langevin 17180 Périgny France Scope

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

Carl Zeiss Meditec Production LLC

1040 South Vintage Ave., Bldg. A Ontario, CA, 91761 United States of America Design, development and manufacture of medical software.

Design and Development, Manufacture and Distribution of Intraocular Lenses, Raw Materials for Intraocular Lenses and Injection Systems for Intraocular Lenses.

