



# EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

## Carl Zeiss Meditec, Inc.

5160 Hacienda Drive  
Dublin, California, 94568-7562  
United States of America

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:

Active Ophthalmologic Devices (MD 1105) 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.	250712 MR2
Certificate unique ID	170758951
Effective date	2019-11-29
Expiry date	2024-05-02
Frankfurt am Main	2019-11-29

## 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**  
**Certificate registration No.: 250712 MR2**  
**Certificate unique ID: 170758951**  
**Effective date: 2019-11-29**

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Device family	Category Code	Class
Corneal Topography System	MD 1105	Ila
Spectral-Domain Optical Coherence Tomography System	MD 1105	Ila
Perimeter, Automatic	MD 1105	Ila
Retinal Optical Coherence Tomography System	MD 1105	Ila
Ophthalmic Fundus Camera	MD 1105	Ila