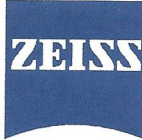


Anexa 11 Perimetru computerizat, Model: Humphrey Field Analyzer 3 (HFA3) 850, Zeiss

Parametri solicitati	Parametri oferiti
<p>Perimetru computerizat Diapazonul temporal maximal: 90°; Stimulus duration 200 ms Visual field testing distance 30 cm Background illumination 31.5 ASB Măsurarea pupilei automat; ReLEYE eye review Marimea stimulării (după Goldmann): I, II, III, IV, V ; Metode: standart W/W, Albastru/ Rosu pe Alb; Albastru pe Galben Fixation control: Heijl-Krakau blind spot monitor, Video eye monitor, Gaze tracking, Head tracking, Vertex monitoring Strategii: SITA Standard, SITA Fast, SITA Faster, Full Threshold, FastPac, SITA-SWAP Specialty test library: Social Security Disability, monocular, binocular, Esterman monocular, binocular, superior 36, 64, Kinetic testing, Custom Static testing Calculator integrat cu perimetru computerizat, cu aplicatie de monitorizare a pacientilor; Ecran tactil (touchscreen); Keyboard Programe si rapoarte: Single Field Analysis (SFA), Glaucoma Hemifield Test (GHT), Visual Field Index (VFI), Guided Progression Analysis (GPA), Mixed GPA, Serial field overview Rețele: DICOM, EMR; Masa/suport cu înălțimea reglabilă electric și 4 roți blocabile; Alimentare curent alternativ 230V (± 10%), 50 Hz.</p>	<p>Perimetru computerizat Diapazonul temporal maximal: 90°; Stimulus duration 200 ms Visual field testing distance 30 cm Background illumination 31.5 ASB Măsurarea pupilei automat; ReLEYE eye review Marimea stimulării (după Goldmann): I, II, III, IV, V ; Metode: standart W/W, Albastru/ Rosu pe Alb; Albastru pe Galben Fixation control: Heijl-Krakau blind spot monitor, Video eye monitor, Gaze tracking, Head tracking, Vertex monitoring Strategii: SITA Standard, SITA Fast, SITA Faster, Full Threshold, FastPac, SITA-SWAP Specialty test library: Social Security Disability, monocular, binocular, Esterman monocular, binocular, superior 36, 64, Kinetic testing, Custom Static testing Calculator integrat cu perimetru computerizat, cu aplicatie de monitorizare a pacientilor; Ecran tactil (touchscreen); Keyboard Programe si rapoarte: Single Field Analysis (SFA), Glaucoma Hemifield Test (GHT), Visual Field Index (VFI), Guided Progression Analysis (GPA), Mixed GPA, Serial field overview Rețele: DICOM, EMR; Masa/suport cu înălțimea reglabilă electric și 4 roți blocabile; Alimentare curent alternativ ~230V, 50 Hz.</p>



EU Declaration of Conformity

in accordance with Directive (EC) 93/42/EEC on Medical Devices

Manufacturer Carl Zeiss Meditec, Inc. 5300 Central Parkway, Dublin, CA 94568, USA

We, Carl Zeiss Meditec, Inc, herewith declare under our sole responsibility that the following Medical Device meets the Requirements of the European Directive 93/42/EEC.

Product identification: UMDNS: Ophthalmic Perimeters, Automated
GMDN: Perimeter, Automatic

Medical Device Name / Trade Name: Humphrey Field Analyzer 3 (HFA3)

Models/Reference: 830, 840, 850, 860

Accessories: Table

Medical Device Class Class IIa

Conformity Assessment Procedure Annex II of MDD 93/42/EEC excluding Section 4

Scope of Application: This Declaration of Conformity is valid for all products manufactured until 2024-05-02

UMDNS classification: 16-918

GMDN Code: 16918

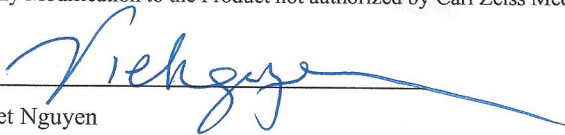
Notified Body: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt – notified under 0297.

Certificate Number: 250712 MR2

EU Representative: Carl Zeiss Meditec AG, Goeschwitzer Strasse 51-52, 07745 Jena, Germany

The device is also in conformance with REGULATION (EU) No 207/2012 on electronic instructions for use of medical devices
DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (recast).

Any Modification to the Product not authorized by Carl Zeiss Meditec, Inc. will invalidate this Declaration.


Viet Nguyen

Director, Quality Management
& Quality Management Representative

Durani Wana Digitally signed by Durani Wana U6WDURAN
U6WDURAN Date: 2021.06.23 17:20:20 -07'00'

Wana Durani
Senior Regulatory Affairs Specialist



EC-CERTIFICATE

(Full quality assurance system)



This is to certify 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.

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:

Imaging devices utilising non-ionizing radiation (MD 1202), Devices utilising ionizing radiation (MD 1401), Devices utilising non-ionizing radiation (MD 1402), Active surgical devices (MD 1104), Active ophthalmologic devices (MD 1105), Software (MD 1111), Non-active functional implants (MD 0203), Non-active medical devices with measuring function (MD 0104), Non-active ophthalmologic devices (MD 0105), Non-active instruments (MD 0106), Non-active device for disinfecting, cleaning and rinsing (MD 0108), 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.	263168 MR2
Certificate unique ID	170774133
Effective date	2021-03-02
Expiry date	2024-05-26
Frankfurt am Main	2021-03-02

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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

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.: 263168 MR2
Certificate unique ID: 170774133
Effective date: 2021-03-02



Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

Device Family / Devices	Category Code	Class
Ophthalmic Examination Unit	MD 1105	Ila
Ophthalmic Lasers and accessories	MD 1105 MD 0105	Ila / IIb
Applanation Tonometer	MD 0104	Im
Posterior-Chamber Intraocular Lens (pseudophakic)		
AT LARA 829MP, AT LARA toric 929M, AT LARA toric 929MP, AT LISA 801, AT LISA 809M, AT LISA 809MP, AT LISA 809MV, AT LISA tri 839MP, AT LISA tri toric 939M, AT LISA tri toric 939MP, AT LISA tri toric 949M, AT LISA tri toric 949MP, AT LISA toric 909M, AT LISA toric 909MP, AT TORBI 709M, AT TORBI 709MP, AT TORBI 719M, AT TORBI 719MP, CT 27SF, CT 37A, CT 47LC, CT 47S, CT SPHERIS 204, CT SPHERIS 209M, CT ASPHINA 404, CT ASPHINA 409M, CT ASPHINA 409MP, CT ASPHINA 409MV, CT ASPHINA 509M, CT ASPHINA 509MP	MD 0203	IIb
CT LUCIA 202, CT LUCIA 602	MD 0203	IIb
CT LUCIA 601P, CT LUCIA 601PY, CT LUCIA 201P, CT LUCIA 611P, CT LUCIA 611PY, CT LUCIA 211P, CT LUCIA 211PY, CT LUCIA 621P, CT LUCIA 621PY, CT LUCIA 221P	MD 0203	III
AT ELANA 841P	MD 0203	III
Anterior-Chamber Intraocular Lens (pseudophakic)		
CT 13A	MD 0203	IIb
Aqueous/Vitreous Humour Replacement Medium	MD 0105	IIb
Z-HYALON, Z-HYALON plus	MD 0105	III
Surgical/Medical Procedure Irrigation Fluid	MD 0108	Ila
Inserters, Intraocular Lens	MD 0105	Ila



Annex to certificate
Certificate registration No.: 263168 MR2
Certificate unique ID: 170774133
Effective date: 2021-03-02



Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

Device Family / Devices	Category Code	Class
Radiosurgery Treatment Systems	MD 0104	Im
	MD 0106	Is
	MD 0106	Ila
	MD 1401	Ilb
INTRABEAM Needle Applicator (accessory to the Radiosurgery Treatment Systems)	MD 0106	III
INTRABEAM Spherical Applicator (accessory to the Radiosurgery Treatment Systems)		
Surgical Microscopes incl. Fluorescence Option	MD 1104	Ila
	MD 1402	Ila
Patient Health Record Information System Application Software	MD 1111	Ila
Operating Room Audio Visual Data/Device Management System	MD 1111	Ila
Intraocular Lens web-based Calculator Software	MD 1111	Ila
Phacoemulsification Systems and accessories	MD 0106	Is
	MD 0105	Ila
	MD 1105	Ilb
Medical Equipment Drape, single-use, sterile	MD 0106	Is
Endoscopes and Endoscopic Visualization Systems		
QEVO	MD 1202	III
Confocal Endomicroscopy	MD 1202	Ila
Sterile Sheath for CONVIVO	MD 0106	III



Humphrey Field Analyzer 3 from ZEISS

Advancing clinical efficiency for glaucoma



**Reduce testing time and
increase insight into glaucoma.**

ZEISS Humphrey Field Analyzer 3



// INNOVATION
MADE BY ZEISS

The ZEISS HFA3 featuring SITA Faster Testing

The Humphrey® Field Analyzer 3 (HFA3) combines everything you value in a Humphrey with expanded testing options and reduced patient test times.

Optimize results for you and your patient.

Expand testing options. Optimize your patient management with new SITA™ Faster 24-2 and 24-2C tests.

Identify progression. Guided Progression Analysis™ (GPA™) helps determine if visual field loss is progressing (where and how fast) to help augment treatment.

Streamline workflow. Reduce set-up time and provide best test results with the Liquid Trial Lens™ and automated eye alignment.

Interact with results. Access HFA3 results and the entire patient test history as well as change baselines on the fly.

Synchronize data for complete patient history. Test patients at any HFA3 or HFAII-i, and generate reports with complete test history.

See the whole picture. HFA is the cornerstone of the Integrated Diagnostic Imaging platform for glaucoma that provides a new level of information for optimal patient management based on visual field function and corresponding OCT structure data.



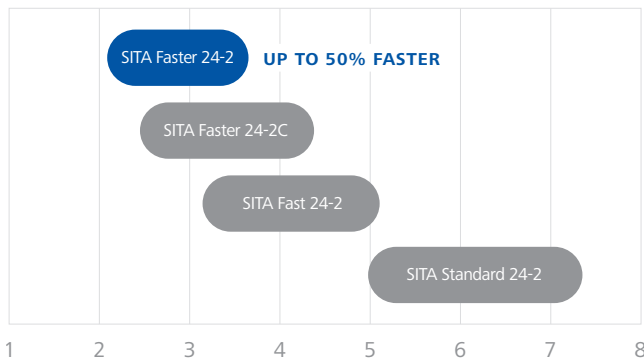
Everything you depend on, only from a Humphrey

The innovations in HFA3 add to the reliable standard that thousands of practices already depend on for essential diagnoses.

SITA "adapts" to patient responses

HFA SITA™ Strategies are the standard of care in visual field testing. SITA makes optimal use of the information contained in the patient's responses, looks at the complete pattern of patient responses while thresholding, and continuously refines the measurements.

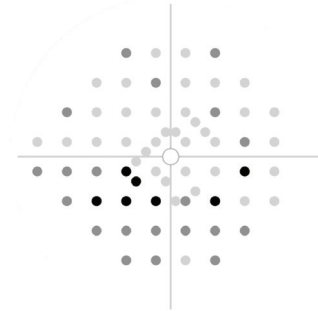
Threshold testing is faster than ever with SITA Faster 24-2



Typical test time ranges in minutes (mean +/- std. dev.)¹

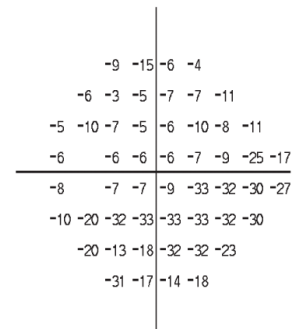
SITA Faster 24-2 improves clinical workflow and patient satisfaction with the fastest test time in HFA threshold testing. Approximately 50% faster than SITA Standard, SITA Faster 24-2 is also about 30% quicker than SITA Fast, yet offers the same reproducibility.

Obtain more information in central visual field



The new **SITA Faster 24-2C** test adds 10 test points to the 24-2 pattern. They were selected to examine areas along physiologically relevant nerve fiber bundles known to be susceptible to glaucomatous defects.¹⁻⁶

Expert analysis of visual field test results



STATPAC™ statistical software compares results to proprietary age normative and glaucoma databases for analyzing changes in the patient's visual field over time.

1 Heijl A¹, Patella VM², Chong LX³, Iwase A⁴, Leung CK⁵, Tuulonen A⁶, Lee GC², Callan T², Bengtsson B⁷. A new SITA perimetric threshold testing algorithm; construction and a multi-center clinical study. *Am J Ophthalmol.* 2018 Oct 15. pii: S0002-9394(18)30592-0. doi: 10.1016/j.ajo.2018.10.010. [Epub ahead of print]

2 Donald C. Hood, ^{ab,*,1} Ali S. Raza, ^{ac,1} Carlos Gustavo V. de Moraes, ^{de,1} Jeffrey M. Liebmann, ^{de,1} and Robert Ritch ^{d,1,1}. Glaucomatous damage of the macula. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3529818/>

3 Ilana Traynis, B.S.,^{1,2} Carlos G. De Moraes, M.D.,^{4,5} Ali S. Raza, B.A.,¹ Jeffrey M. Liebmann, M.D.,^{4,5} Robert Ritch, M.D.,^{4,6} and Donald C. Hood, Ph.D.^{1,3}. The Prevalence and Nature of Early Glaucomatous Defects in the Central 10° of the Visual Field. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4204644/>

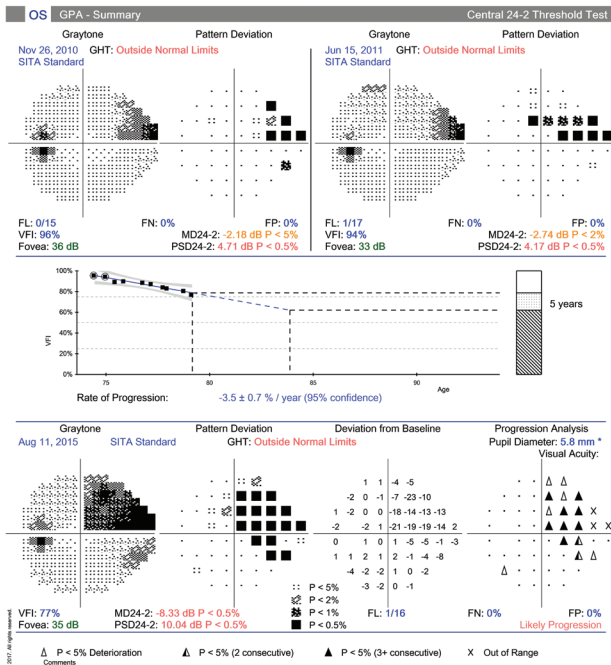
4 De Moraes CG¹, Hood DC², Thenappan A³, Girkin CA⁴, Medeiros FA⁵, Weinreb RN⁵, Zangwill LM⁵, Liebmann JM⁶. Visual Fields Miss Central Defects Shown on 10-2 Tests in Glaucoma Suspects, Ocular Hypertensives, and Early Glaucoma. *Ophthalmology.* 2017 Oct;124(10):1449-1456. doi: 10.1016/j.ophtha.2017.04.021. Epub 2017 May 24. 24-2. <https://www.ncbi.nlm.nih.gov/pubmed/28551166> *Invest Ophthalmol Vis Sci.* 2014 Feb 3;55(2):632-49. doi: 10.1167/iovs.13-13130.

5 Hood DC¹, Slobodnick A, Raza AS, de Moraes CG, Teng CC, Ritch R. Early glaucoma involves both deep local, and shallow widespread, retinal nerve fiber damage of the macular region. <https://www.ncbi.nlm.nih.gov/pubmed/24370831>

6 Donald C. Hood,^{1,2} Matthew Nguyen,¹ Alyssa C. Ehrlich,¹ Ali S. Raza,^{1,3} Ieva Sliesoraityte,^{4,5} Carlos G. De Moraes,² Robert Ritch,^{6,7} and Ulrich Schiefer^{4,8}. A Test of a Model of Glaucomatous Damage of the Macula With High-Density Perimetry: Implications for the Locations of Visual Field Test Points. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4064621/>

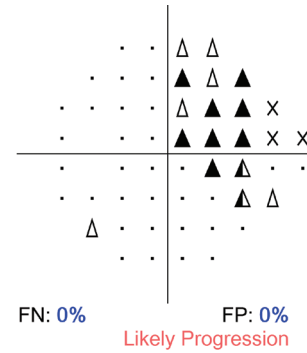


Inform your decision-making with GPA



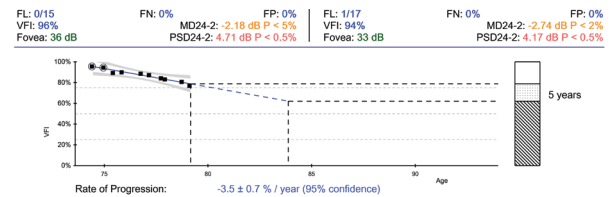
GPA™ (Guided Progression Analysis) is designed to help you identify where, and how fast, defects are progressing. GPA allows transition to new SITA tests while maintaining analysis of the complete patient history.

Identify consecutive change at each test point



Progression Analysis Probability Plot is designed to identify statistically significant progression events in consecutive visits at individual test points. GPA Alert displays a plain language message about the likelihood of disease progression.

Visualize rate of progression



Visual Field Index™ (VFI) is a measure of the patient's overall visual function as compared to an age-adjusted normal population. VFI trend analysis helps differentiate rapid versus slow progressing visual field loss.

HFA3 makes visual field testing faster and easier than ever

Simple to operate

- 1 Liquid Trial Lens technology** reduces setup time by automatically loading each patient's refractive correction from the previous exam.
- 2 Automated eye alignment** centers the patient's eye to the trial lens and adjusts to the patient during the test to provide fast setup and best results.
- 3 With the intuitive SmartTouch interface** you simply select the patient's name and press start to begin testing.



Enhancing workflow from patient testing to report review



New Review Software delivers comprehensive analysis and improves digital workflow.

- **Quickly access** HFA reports in every exam lane.
- **Modify reports on-the-fly** to include and exclude tests, reset baselines and follow up on tests.
- **Simple visual reports** foster clear patient communication, which may help improve compliance.

Data Synchronization automatically updates and integrates patient tests from any connected HFA3. HFA-III contributes tests to HFA3, enabling you to use existing HFA-III devices to supplement testing capacity.

Technical data Specifications

Choose the HFA3 that's right for you

Specifications	HFA3				Humphrey Matrix 800	Humphrey FDT
	830	840	850	860		
Test specifications						
Maximum temporal range (degrees)	90				30	30
Stimulus duration	200 ms				300 ms	200-400 ms
Visual field testing distance	30 cm				Infinity	Infinity
Background illumination	31.5 ASB				100 cd/m ²	100 cd/m ²
Threshold test library						
N-30					•	•
C-20						•
24-2, 30-2, 10-2, Macula	•	•	•	•	•	
60-4, Nasal step	•	•	•	•		
Threshold test strategies						
SITA Standard, SITA Fast, SITA Faster, Full Threshold, FastPac	•	•	•	•		
SITA-SWAP			•	•		
MOBS					•	•
ZEST					•	
Suprathreshold test library						
C40, C76, C80	•	•	•	•		
C64, C-Armaly	•	•	•	•		
C-20						•
N-30					•	•
24-2					•	
Peripheral test patterns	•	•	•	•		
Suprathreshold test modes						
Age corrected	•	•	•	•	•	•
Threshold related, Single intensity	•	•	•	•		
Specialty test library						
Social Security Disability, monocular, binocular	•	•	•	•		
Esterman monocular, binocular, superior 36, 64	•	•	•	•		
Kinetic testing		•	•	•		
Custom Kinetic testing		•	•	•		
Custom Static testing	•	•	•	•		

Features	HFA3				Humphrey Matrix 800	Humphrey FDT
	830	840	850	860		
Fixation control						
Heijl-Krakau blind spot monitor	•	•	•	•	•	•
Video eye monitor	•	•	•	•		•
Gaze tracking		•	•	•		
Head tracking		•	•	•		
Vertex monitoring			•	•		
Operator interface						
Display	Touchscreen LCD				LCD	LCD
Keyboard	•	•	•	•		•
Stimulus						
Frequency doubling					•	•
White-on-white	•	•	•	•		
Red- or blue-on-white		•	•	•		
Blue-on-yellow (SWAP)			•	•		
General testing features						
Stimulus sizes	Goldmann I-V				10°	2°, 5°, 10°
Foveal threshold testing		•	•	•		
Automatic pupil measurement		•	•	•		
Liquid Trial Lens (AutoTLC)				•		
RelEYE eye review			•	•		
Test storage						
User-defined	•	•	•	•		•
Software features						
Single Field Analysis (SFA)	•	•	•	•		
Glaucoma Hemifield Test (GHT)	•	•	•	•		•
Visual Field Index (VFI)	•	•	•	•		
Guided Progression Analysis (GPA)	•	•	•	•		
Mixed GPA	•	•	•	•		
Serial field overview	•	•	•	•		•
Networking	•	•	•	•		•
FORUM Connectivity	•	•	•	•		•
DICOM Connectivity	•	•	•	•		•
Printer						
Thermal printer					•	
Native generic PCL 3, PCL 5 and postscript printer support for local, shared and networked printers						•
Native postscript printer support for network capable printers	Optional					
Data storage, retrieval and analysis						
Hard drive	500 GB					250 GB
USB	•	•	•	•		•
CD-R/W drive						•
Dimensions						
Height	23" (58 cm)				17" (43 cm)	17" (43 cm)
Width	20" (51 cm)				10" (25 cm)	12.2" (31 cm)
Depth	18" (46 cm)				19" (48 cm)	33.5" (85 cm)
Weight	63 lbs (28.7 kg)				19 lbs (8.6 kg)	37.5 lbs (17.4 kg)
Electrical requirements						
	100-120V~, 50/60Hz, 4.0A 230V~, 50/60Hz, 1.8A				100-120V, 50/60Hz 230V, 50/60Hz	100-240V~, 50/60Hz, 200VA max
Standards						
Meets UL, CSA and CE standards	•	•	•	•	•	•

See the whole picture

Integrated Diagnostics Imaging platform for Glaucoma

Glaucoma management is evolving to require a new diagnostic environment to support your clinical assessment when and where you need it.

The Integrated Diagnostics Imaging platform delivers information critical to understanding and managing your patients by offering connection to multi-modality data sets. The combined analysis of HFA3 and CIRRUS™ HD-OCT lets you observe, identify and evaluate structural and functional changes earlier, for better glaucoma management.



ZEISS Integrated Diagnostic Imaging - Glaucoma



0297

Humphrey Field Analyzer 3



Carl Zeiss Meditec, Inc.
5160 Hacienda Drive
Dublin, CA 94568
USA
www.zeiss.com/HFA3
www.zeiss.com/med/contacts



Carl Zeiss Meditec AG
Goeschwitzer Str. 51-52
07745 Jena
Germany
www.zeiss.com/med/contacts

EN_31_020_00111 Printed in Germany, CV/XII/2018, International Edition.
The contents of the brochure may differ from the current status of approval of the product or service offering in your country. Please contact our regional representatives for more information. Subject to changes in design and scope of delivery and due to ongoing technical development. Humphrey, HFA, Liquid Trial lens, CIRRUS, Guided Progression Analysis, GPA, SITA, Visual Field Index, VFI, STATPAC, Humphrey FDT, and Humphrey Matrix are either trademarks or registered trademarks of Carl Zeiss Meditec AG or other companies of the ZEISS Group in Germany and/or other countries.
© Carl Zeiss Meditec Inc., 2018. All rights reserved.



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

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

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



Annex to certificate
Certificate registration No.: 263168 MP2016
Certificate unique ID: 170775820
Effective date: 2021-11-19

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

Location

Scope

462969

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.

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
Certificate registration No.: 263168 MP2016
Certificate unique ID: 170775820
Effective date: 2021-11-19

Carl Zeiss Meditec AG

Goeschwitzer Strasse 51 - 52
07745 Jena
Germany

Location

Scope

494569

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.

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.