

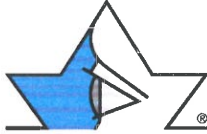


America

CERTIFICATE

No. QS6 021454 0026 Rev. 00

Certificate Holder:



OCULUS

Certification Mark:

OCULUS

Optikgeräte GmbH

Münchholzhäuser Str. 29

35582 Wetzlar

GERMANY



Scope of Certificate:

**Design and Development, Manufacturing,
Distribution and Servicing of Ophthalmic
Diagnostic Devices**

Standard(s):

ISO 13485:2016

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA
FDA, MHLW / PMDA.
See attached for listing of specific
regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website
<http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder>

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No:

31-713-8956

Effective Date:

2018-08-20

Expiry Date:

2021-08-19

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Date of Issue: 2018-09-20

(Arie Henkin)

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Regulatory Requirements: Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies):

OCULUS Optikgeräte GmbH
Münchholzhäuser Str. 29, 35582 Wetzlar, GERMANY

OCULUS Optikgeräte GmbH
Sudetenstrasse 52, 35581 Wetzlar, GERMANY

Facility Scopes:

OCULUS Optikgeräte GmbH
Münchholzhäuser Strasse 29, 35582 Wetzlar, GERMANY

Design and Development, Manufacturing, Distribution and Servicing
of Ophthalmic Diagnostic Devices
DUNS No: 31-713-8956

OCULUS Optikgeräte GmbH
Sudetenstrasse 52, 35581 Wetzlar, GERMANY

Manufacturing of Components for Ophthalmic Diagnostic Devices
DUNS No: 31-713-8956

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(Arie Henkin)

USA-Letter / 07.17
CERTIFICATE ◆ ZERTIFIKAT ◆ CERTIFICADO ◆ CERTIFICAT