



America

# CERTIFICATE

No. QS6 021454 0026 Rev. 03

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 [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)

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

REPs Facility ID:

F001713

Effective Date:

2022-08-09

Expiry Date:

2024-08-19

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Date of Issue: 2022-08-19

( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services

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## Regulatory Requirements: Audit/Certification Criteria

### Australia

Therapeutic Goods (Medical Devices) Regulations 2002  
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

### Brazil

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

### Canada

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

### Japan

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

### United States

- 21 CFR Part 803  
- 21 CFR Part 806  
- 21 CFR Part 807 – Subparts A to D  
- 21 CFR Part 820

## Facility(ies):

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

OCULUS Optikgeräte GmbH  
Sudetenstrasse 52, 35581 Wetzlar, GERMANY

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**Facility Scopes:**

**OCULUS Optikgeräte GmbH**

Münchholzhäuser Str. 29, 35582 Wetzlar, GERMANY

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

REPs Facility ID: F001713

**OCULUS Optikgeräte GmbH**

Sudetenstrasse 52, 35581 Wetzlar, GERMANY

Manufacturing of Components for Ophthalmic  
Diagnostic Devices

REPs Facility ID: F001713

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