

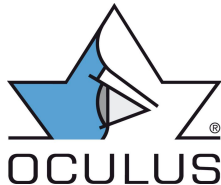


America

CERTIFICATE

No. QS6 021454 0026 Rev. 02

Certificate Holder:



OCULUS
Optikgeräte GmbH
 Münchholzhäuser Str. 29
 35582 Wetzlar
 GERMANY

Certification Mark:



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

REPs Facility ID:

F001713

Effective Date:

2021-09-17

Expiry Date:

2022-08-19

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Date of Issue: 2021-10-05

(Michael Ogunleye)
 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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