



# Certificate

No. Q5 021454 0025 Rev. 04

Holder of Certificate:



**OCULUS**

Certification Mark:

**OCULUS**

**Optikgeräte GmbH**

Münchholzhäuser Str. 29  
35582 Wetzlar  
GERMANY



Scope of Certificate:

**Design and Development, Manufacturing,  
Distribution and Servicing of sterile non-active  
Ophthalmic Diagnostic Devices and non-sterile  
active Ophthalmic Diagnostic Devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 021454 0025 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5 021454 0025 Rev. 04)

Report No.: 713265822

Valid from: 2024-01-15

Valid until: 2024-10-21

Date, 2024-01-15

Christoph Dicks

Head of Certification/Notified Body

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**Applied Standard(s):** ISO 13485:2016  
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)  
Medical devices - Quality management systems -  
Requirements for regulatory purposes

**Facility(ies):** **OCULUS Optikgeräte GmbH**  
Münchholzhäuser Str. 29, 35582 Wetzlar, GERMANY

Design and Development, Manufacturing, Distribution and  
Servicing of sterile non-active Ophthalmic Diagnostic Devices and  
non-sterile active Ophthalmic Diagnostic Devices.

**OCULUS Optikgeräte GmbH**  
Sudetenstrasse 52, 35581 Wetzlar, GERMANY

Manufacturing of Components for non-sterile non-active  
Ophthalmic Diagnostic Devices.

**OCULUS Optikgeräte GmbH**  
Siegmond Hiepe Straße 28-32, 35578 Wetzlar, GERMANY

Servicing of non-sterile active Ophthalmic Diagnostic Devices.