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Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
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Product Service

# EC Certificate

Full Quality Assurance System  
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 021454 0027 Rev. 00**

## Manufacturer:

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

## Facility(ies):

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

OCULUS Optikgeräte GmbH  
Sudetenstrasse 52, 35581 Wetzlar, GERMANY

## Product Category(ies): Active diagnostic ophthalmic devices

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

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Stefan Preiß  
Head of Certification/Notified Body