Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD 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.

Report No.: 713162431

Valid from: 2019-09-19
Valid until: 2024-05-26

Date, 2019-09-19

Stefan Preiß
Head of Certification/Notified Body

Digitally signed by Rusu Cristina
Date: 2023.06.10 17:41:26 EEST
Reason: MoldSign Signature
Location: Moldova

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany