



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



Product Service

EC Certificate

Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V

(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 021454 0028 Rev. 00

Manufacturer

OCULUS

Optikgeräte GmbH

Münchholzhäuser Str. 29

35582 Wetzlar

GERMANY

Facility(ies):

OCULUS Optikgeräte GmbH

Sudetenstrasse 52, 35581 Wetzlar, GERMANY

OCULUS Optikgeräte GmbH

Münchholzhäuser Str. 29, 35582 Wetzlar, GERMANY

Product

Category(ies):

Binocular Indirect Ophthalmic-Microscope,

disposable, sterile

Optic Set for OP-microscope, disposable, sterile

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:

713162436

Valid from:

2019-10-23

Valid until:

2024-05-26

Date,

2019-10-23

Stefan Preiß

Head of Certification/Notified Body