TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60153522 0001

Report No.: 3330263 090

Manufacturer:
ROLAND CONSULT
Stasche & Finger GmbH
Heidelberger Str. 7
14772 Brandenburg an der Havel
Deutschland

Products:
Diagnostic systems for ophthalmology

(see attachement for products included)

Replace Certificate, Registration No.: DD 60142014 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

TÜV Rheinland LGA Products GmbH - Zertifizierungsstelle - TÜVRheinland

Effective Date: 2020-12-04

Date: 2020-12-04

Dipl.-Ing. (FH) D. Wiedemuth

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60153522 0001
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Products included:

- RETI-port/scan 21
- Stimulator Monitor TFT 19"
- Ganzfeld Q450 C
- Ganzfeld Q450 SC
- MINIganzfeld I8
- BABYflash E130
- DARK-adaptometer

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland

Date: 2020-12-04

D. Wiedemuth

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