TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60118818 0001

Report No.: 21176353 009

Manufacturer:
LEONI Fiber Optics GmbH
Mühldamm 6
96524 Neuhaus-Schierschnitz
Deutschland

Products: Medical Laser Probes

(see attachment for sites included)

Replaces Certificate, Registration No.: HD 60074994 0001

Expiry Date: 2022-03-05

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 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 II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2017-06-01

Date: 2017-06-01

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Dipl.-Ing. F. Bley

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.: HD 60118818 0001
Report No.: 21176353 009

Manufacturer: LEONI Fiber Optics GmbH
Mühldamm 6
96524 Neuhaus-Schierschnitz
Deutschland

Site included:

LEONI Fiber Optics GmbH
Nalepastraße 170-171
12459 Berlin
Germany

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2017-06-01

Dipl.-Ing. F. Bley