EC Certificate

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

Registration No.: HD 60105768 0001

Report No.: 21232818 001

Manufacturer:
Asclepion Laser Technologies GmbH
Brüsseler Str. 10
07747 Jena
Deutschland

Products: see attachment for products included

Replaces Approval, Registration No.: HD 60097279 0001

Expiry Date: 2020-12-02

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: 2015-12-03

Date: 2015-12-01

Notified Body

Dipl.-Ing. D. Meier

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 60105768 0001
Report No.: 21232818 001

Manufacturer: Asclepion Laser Technologies GmbH
Brüsseler Str. 10
07747 Jena
Deutschland

Products included:

- surgical and dermatological lasers
- electrotherapeutical medical devices
- sterile and re-sterilisable laser fibers
- Laser supply systems, light fibers

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2015-12-01

Dipl.-Ing. D. Meier