TÜVRheinland®

EC Certificate

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

Registration No.: HD 60114542 0001

Report No.: 21216761 006

Manufacturer:
GME German Medical Engineering GmbH
Grimmstr. 23
90491 Nürnberg
Deutschland

Products:
- Diode Lasers
- Excimer Lamps

(see attachment for sites included)

Replaces Certificate, Registration No.: HD 60101177 0001

Expiry Date: 2017-11-11

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: 2016-10-18

Date: 2016-10-18

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Dipl.-Ing. I. Munkler

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 60114542 0001
Report No.: 21216761 006

Manufacturer: GME German Medical Engineering GmbH
Grimmstr. 23
90491 Nürnberg
Deutschland

Site included:

- GME German Medical Engineering GmbH
  Albert-Rupp-Str. 2
  91052 Erlangen
  Germany

Activities: Design and development

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2016-10-18

Dipl.-Ing. I. Munkler