

**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

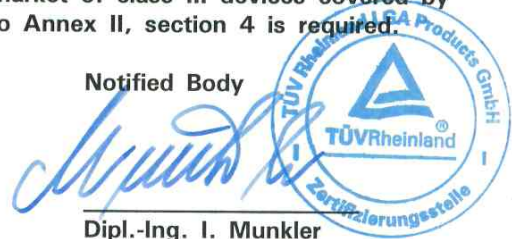
**Expiry Date:** 2017-11-11

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



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.

**TÜV Rheinland  
LGA Products GmbH  
Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

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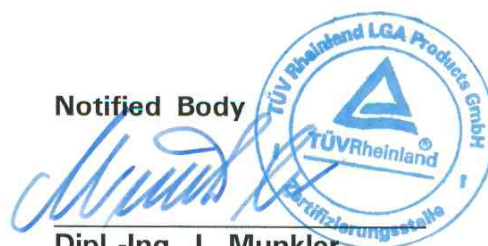
Site included:

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

Activities: Design and development

**Date:** 2016-10-18

**Notified Body**



**Dipl.-Ing. I. Munkler**