

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

Registration No.: HD 60101113 0001

Report No.: 21231126 002

Manufacturer: SiCAT GmbH & Co. KG
Brunnenallee 6
53177 Bonn
Deutschland

Products: Software for dental applications
(see attachment for products and sites included)
Replaces Certificate, Registration No.: HD 60091222 0001

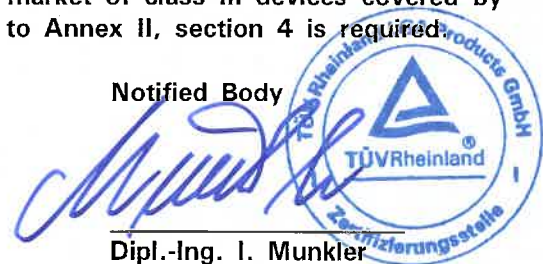
Expiry Date: 2020-06-22

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: 2015-06-23

Date: 2015-06-18

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**

Registration No.: HD 60101113 0001
Report No.: 21231126 002

Manufacturer: SiCAT GmbH & Co. KG
Brunnenallee 6
53177 Bonn
Deutschland

Products included:

- SiCAT Function:
Software for dental diagnostics and therapy planning
- GALILEOS Implant:
Software for dental implant planning
- SiCAT Implant:
Software for dental diagnostics and implant planning

Aspects of manufacture concerned with the conformity of software and hardware with measuring function for dental medicine with the metrological requirements:


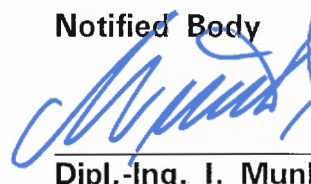
- SiCAT JMT+

Site included:

- SiCAT GmbH & Co. KG
Schwertberger Straße 14-16, 53177 Bonn
Germany
Activity: Design and development and manufacturing

Date: 2015-06-18

Notified Body



Dipl.-Ing. I. Munkler