EC Certificate

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

TÜVRheinland®

Registration No.: HD 60094402 0001

Report No.: 21210582 001

Manufacturer:
Biodenta Swiss AG
Tramstr. 16
9442 Berneck
Switzerland

Products:
Dental implant systems and associated instruments, prosthetic products and dental ceramics
(see attachment for products included)

Replaces approval, registration no. HD 60030026 0001

Expiry Date: 2019-06-15

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: 2014-06-16

Date: 2014-06-16

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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.

TÜVRheinland®

Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60094402 0001
Report No.: 21210582 001

Manufacturer:
Biodenta Swiss AG
Tramstr. 16
9442 Berneck
Switzerland

Included products:

- Dental implants
- Healing caps and closure screws
- Surgical instruments
- Prosthetic products
- Dental ceramics

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Date: 2014-06-16

Dipl.-Ing. D. Meier