TÜVRheinland®

EC Certificate

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

Registration No.: HD 60089620 0001

Report No.: 21206371 001

Manufacturer:
Drendel + Zweiling DIAMANT GmbH
Schürenbreder Weg 27
32689 Kalletal
Deutschland

Products:
Non-active dental equipment and instruments

(see attachment for products included)

Replaces Approval, Registration No.: HD 60023864 0001

Expiry Date: 2019-01-08

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.

Notified Body

Effective Date: 2014-01-20

Date: 2014-01-20

Dr. K. Kluge

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

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. 2

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60089620 0001
Report No.: 21206371 010

Manufacturer: Drendel + Zweiling DIAMANT GmbH
Schürenbreder Weg 27
32689 Kalletal
Deutschland

Products included:

- Rotary instruments for dentistry
- Rotary instruments for orthopedics and surgery
- Rotary endodontic instruments

Notified Body

TÜV Rheinland LGA Products GmbH TÜVRheinland Fertinzierungsstelle

Dr. V. Kluge

Dr. K. Kluge

Date: 2018-05-03