EC Certificate

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

Registration No.: HD 60135336 0001

Report No.: 21206371 012

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 60089620 0001

Expiry Date: 2024-01-08

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.

Effective Date: 2019-01-09

Date: 2019-01-04

Notified Body

Dr. K. Kluge

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. 1

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60135336 0001
Report No.: 21206371 013

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
- Manual instruments and tools for use in dentistry

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland®

Notified Body

Date: 2019-12-18

Dr. T. Kießling

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