TÜVRheinland®

EC Certificate

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

Registration No.: HD 60075582 0001

Report No.: 13011853 001

Manufacturer: DiaDent Group International
No. 626, Yeonje-ri,
Gangoe-myeon, Cheongwon-gun,
Chungcheongbuk-do, 363-951,
South Korea

Products: Design and Development, Manufacture of Sterile Dental Devices, Non-Sterile Dental Devices and Active Dental Instruments for Dental Surgery

(see attachment for products included)

Expiry Date: 2017-03-06

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: 2012-09-03

Date: 2012-09-03

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Dipl.-Ing. O. Masur

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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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60075582 0001
Report No.: 13011853 001

Manufacturer: DiaDent Group International
No. 626, Yeonje-ri,
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Products included:

- Gutta Percha Obturators
- Endodontic Filling Materials
- Pit and Fissure Sealants
- Bonding Agents
- Dental Composite Restorative Materials
- Root Canal Filling Material
- Temporary Filling Material
- Root Canal Cleanser
- Phosphoric Etching Gel
- Guttapercha Obturation System

Date: 2012-09-03

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Notified Body

Dipl.-Ing. O. Masur