TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60075581 0001

Report No.: 13011853 001

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

Products:
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 V 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 V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2012-09-03

Date: 2012-09-03

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60075581 0001
Report No.: 13011853 001

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South Korea

Products included:

- Gutta Percha Points
- Apex Locators
- Endodontic Files

For the following medical devices the scope covers only the aspects of manufacture concerned with securing and maintaining sterile conditions:

- Sterile Paper Points

Date: 2012-09-03

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

Notified Body

Dipl.-Ing. O. Masur