EC Certificate

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

Registration No.: HD 60102396 0001

Report No.: 12022722 001

Manufacturer:
DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do, 28161
Republic of Korea

Products:
See attachment for products included

Replaces Approval, Registration NO.: HD 60096170 0001

Expiry Date: 2020-06-01

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: 2016-01-15

Date: 2016-01-15

Notified Body

M.Sc. M. Aihara

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.: HD 60102396 0001
Report No.: 12022722 001

Manufacturer:
DiaDent Group International
16, Osongsaengmyeong 4-ro
Osong-eup
Heungdeok-gu, Cheongju-si
Chungcheongbuk-do, 28161
Republic of Korea

Products:

- Gutta Percha Obturators
- Endodontic Filling Materials
- Bonding Agents
- Pit and Fissure Sealants
- Light-cured Composite Resin
- Light-cured Radiopaque Flowable Composite Resin
- Root Canal Filling Material
- Temporary Filling Material
- Polymer-based Filling Restorative Material
- Root Canal Cleanser
- Etching Agents
- Hydraulic Temporary Restorative Material
- Dual-cured Composite Resin
- Dental Temporary Cement
- Root Canal Sealing Material

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Notified Body

Date: 2016-01-15

M.Sc. M. Aihara

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