

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

Registration No.: HD 60149568 0001

Report No.: 12022722 013

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 60102396 0001

Expiry Date: 2024-05-26

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: 2020-05-25

Date: 2020-05-25

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.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

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Report No.: 12022722 013

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Products:

- Gutta Percha Obturators
- 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



Date: 2020-05-25

Notified Body

M. Aihara
M.Sc. M. Aihara