

## **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

M.Sc. M. Aihara

GA ProNotified Body

TÜVRheinla

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.



Doc. 1/1, Rev.0

## TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: HD 60149568 0001

Report No.: 12022722 013

Manufacturer: DiaDent Group International

16, Osongsaengmyeong 4-ro

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Heungdeok-gu, Cheongju-si Chungcheongbuk-do, 28161

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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
TÜVRheinland
III

M.Sc. M. Aihara