

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

Registration No.: DD 60149569 0001

Report No.: 12022722 017

Manufacturer: DiaDent Group International

16, Osongsaengmyeong 4-ro

Osong-eup

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

Republic of Korea

Products: Endodontic Files, Sterile Paper Points, Gutta Percha Points,

Disposable Sterile Irrigation Probe Needle Tips and Gutta

Percha Obturation System

Replaces Approval, Registration No.: DD 60102395 0001

**Expiry Date:** 2024-05-26

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: 2020-05-25

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M.Sc. M. Aihara

GA ProduNotified Body

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.