EC Certificate

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

Registration No.: DD 60102395 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:

Endodontic Files, Sterile Paper Points, Gutta Percha Points, Disposable Sterile Irrigation Probe Needle Tips and Gutta Percha Obturation System

Replaces Approval, Registration No.: DD 60096169 0001

Expiry Date: 2020-06-01

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: 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.