EC Declaration of Conformity

Doc No : DC-001
Rev.No : 9

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

Authorized Representative :
DiaDent Europe B.V.
Antennestraat 70, 1322AS Almere, the Netherlands

We, the manufacturer, herewith declare that the products

Gutta Percha Points

(including system components and accessories)
GMDN : 31872

meet the provisions of The Medical Devices Directive 93/42/EEC amended by 2007/47/EC which apply to them.

The medical device has been assigned to Class IIa(Rule 8) according to Annex IX of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex V of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC.

Compliance of the designated product with The Medical Devices Directive 93/42/EEC amended by 2007/47/EC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No : DD 60149569 0001
Issue date : 2020-05-25
Expiry date : 2024-05-26

following the procedure relating to the EC Declaration of Conformity set out in Annex V of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC

The above mentioned declaration of conformity is exclusively under the responsibility of

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

2020-06-01
Date

DiaDent Group International
16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do,
Tel

Signature