

EC Declaration of Conformity

Doc No

DC-088

Rev.No

3

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

EvoFill Duo

(including system components and accessories)

45247

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 11) according to Annex IX of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC. It bears the mark

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 Vof the Medical Devices Directive 93/42/EEC amended by 2007/47/EC

he 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

eongju-si, Chungcheonabuk-do Tel:82-43-266-2315

DiaDent Group International

16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea Fax: 82-43-262-8658

Tel: 82-43-266-2315 http://www.diadent.co.kr

E-mail: diadent@diadent.co.kr

