DiaDent® Serving 122 countries around the world

EC Declaration of Conformity

Doc No : DC-077
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

DiaFil Core™automix

UMDNS-Code: **16-724**

meet the provisions of Directive 93/42/EEC and 2007/47/EEC which apply to them.

The medical device has been assigned to class IIa (Rule 8)according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60102396 0001
Issue date: 2016-01-15
Expiry date: 2020-06-01

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

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

2016.01.15

Place , date

signature,

DiaDent Group International
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