

EC Declaration of Conformity

Doc No : DC-102

Rev.No : 2

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

DiaDent[®]
 We, the manufacturer, herewith declare that the products

Dia-X File

GMDN : 40529

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 6) 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

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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[®]
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Signature