EC Declaration of Conformity

Doc No :   DC-113

Rev.No :   1

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

DIA-ROOT BIO MTA

(including system components and accessories)

GMDN   :   36095

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

C E 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II
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	:	HD 60149568 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 II 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
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Cheongju-si, Chungcheongbuk-do, 28161, Korea
Tel : 82-43-266-2315   Fax : 82-43-262-8658

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Signature

C E Certified ISO 13485