

EC Declaration of Conformity

Doc. No: DC-114

Rev.No: -1-

Manufacturer:**DiaDent Group International**

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

Agent:**DiaDent Group International Inc.**

11-3871 North Fraser Way, Burnaby,
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Canada, V5J5G6



We, the manufacturer, herewith declare that the products

DIA-ROOT BIO Sealer**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

CE 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

Place, date

DiaDent[®]**DiaDent Group International**

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