

EC Declaration of Conformity

Doc No :

DC-105

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 Temp

(including system components and accessories)

GMDN

31783

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 7) 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 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

Cheongju-si, Chungcheongbuk-do, 28161 Signature Tel: 82-43-266-2315

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