

## EC Declaration of Conformity

Doc No : DC-104

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

 We, the manufacturer, herewith declare that the products

**Dia-Duo (Duo-Gun, Duo-Pen)**

(including system components and accessories)

GMDN : 45247

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 11) 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 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

Issue date : 2020-05-25

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 Group International**  
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Signature