

Doc No

DC-001

Rev.No

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

We, the manufacturer, herewith declare that the products

### **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

## **Gutta Percha Points**

**GMDN** 

31872

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

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

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

DiaDent Group International

Date

saengmyeong 4-ro. Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheong buk-do, 28161, Korea Fax: 82-43-262-8658

Signature

Certified 50 13485



DiaDent Group International

16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea Fax: 82-43-262-8658

Tel: 82-43-266-2315 http://www.diadent.co.kr



Doc No

DC-016

Rev.No

6

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu,

Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

We, the manufacturer, herewith declare that the products

### **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

# Sterile Paper Point

**GMDN** 

38777

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

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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 Vof the Medical Devices Directive 93/42/EEC amended by 2007/47/EC

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

DiaDent Group International

Date

ngsaengmyeorg 4-ro, Osong-eup, Heungdeok Cheongju-si, Chungcheong buk-do, 28161, Korea

Signature

Certified 50 1348



DiaDent Group International 16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea

Tel: 82-43-266-2315 http://www.diadent.co.kr



Doc No

DC-076

Rev.No

6

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

We, the manufacturer, herewith declare that the products

## **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

## e-Temp

**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

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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

e 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

DiaDent Group International

Date

el: 82-43-266-2315 Fax: 82-43-2

**DiaDent Group International** 

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

Tel: 82-43-266-2315

Fax: 82-43-262-8658



http://www.diadent.co.kr



Doc No :

DC-034

Rev.No

7

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

zoror, republic of Rolea

Authorized Representative:

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

We, the manufacturer, herewith declare that the products

### FILE MEASURE SET

(Plastic)

**GMDN** 

64813

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 ClassI(Rule 1) according to Annex IX of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC. It bears the mark

C € 0197

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

N/A

Issue date

N/A

Expiry date

N/A

following the procedure relating to the EC Declaration of Conformity set out in Annex VIIof
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

Dia Dent

2020-06-01

DiaDent Group International

Date

16. Osongsaengmyeong 4-ro. Osong-eup, Heungdeok-g **Signature** Cheongju-si, Chungcheong buk-do, 28161, Korea

This 82-43-26 Group Internation 282-8658

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

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Doc No :

DC-074

Rev. No.

#### 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

## STERI-IRRIGATION TIPS SIDE OPEN TYPE

**GMDN** 

64403

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

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## TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No

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## **DiaDent Group International**

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

2020-06-01

DiaDent Group International

Date

Signature Chungcheong buk-do, 28161, Korea

DiaDent Group International

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

Tel: 82-43-266-2315 http://www.diadent.co.kr





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

(P)

We, the manufacturer, herewith declare that the products

## **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

## Dia Temp

**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

C € 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.

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## TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No

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### **DiaDent Group International**

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

Dia Dent

2020-06-01 Date DiaDent Group International

Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-

**DiaDent Group International** 

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

Tel: 82-43-266-2315 http://www.diadent.co.kr





Doc No

DC-106

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 Flow

(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

C € 0197 Bent

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

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## **DiaDent Group International**

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

Dia Dent ®

2020-06-01

DiaDent Group International

Date

16. Osongsængmyeong 4-ro. Osong-eup, Heungdeok-g Cheongju-si, Chungcheong buk-do. 28161, Kori Tel: 82-43-266-2315 Fax: 82-43-262-863

Signature

2-43-266-2315 Fax: 82-43-262-8658

DiaDent Group International

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

Tel: 82-43-266-2315 http://www.diadent.co.kr





Doc No

DC-113

Rev.No

### 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** 

60510

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

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## TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

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# **DiaDent Group International**

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

2020-06-01

DiaDent Group Internationa

Date

-43-266-2315

Certified 50 1348



**DiaDent Group International** 

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

Tel: 82-43-266-2315 http://www.diadent.co.kr



Doc No

DC-085

Rev.No

5

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

We, the manufacturer, herewith declare that the products

## Authorized Representative :

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

## Dia-PT 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

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# TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

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## **DiaDent Group International**

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

2020-06-01

DiaDent Group International

Cheongju-si, Chungcheong buk-do. 2816:

Signature

Certified 150 1348



**DiaDent Group International** 16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea

Tel: 82-43-266-2315 Fax: 82-43-262-8658 http://www.diadent.co.kr



Doc No

DC-086

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-PROSEAL

(including system components and accessories)

**GMDN** 

45227

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

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## TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No

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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

DiaDent Group International

2020-06-01 Date

Signature

Certified ISO 13485



DiaDent Group International 16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea

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Doc No

DC-103

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

# DiaPrep Pro

(including system components and accessories)

**GMDN** 

45500

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

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# TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No

HD 60149568 0001

Issue date

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2024-05-26

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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

DiaDent Group International

Date

Osongsaengmyeong 4-ro. Osong-eup, Heungdeok-gu, Signature Chungcheong buk-do, 28161, Kore

**DiaDent Group International** 

16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea Fax: 82-43-262-8658

Tel: 82-43-266-2315 http://www.diadent.co.kr





Doc No

DC-109

Rev.No

2

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

We, the manufacturer, herewith declare that the products

### **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

### **Dia Fil**

(including system components and accessories)

**GMDN** 

35870

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

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# TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431, Nürnberg, Germany

Certificate No

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### **DiaDent Group International**

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

2020-06-01

DiaDent Group International

Date

Osongsaengmyeong 4-ro. Osong-eup, Heungdeok-guŞignature

heongju-si. Chungcheong buk-do, 28161, Korea DiaDent Group International-8658

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

Tel: 82-43-266-2315 http://www.diadent.co.kr





Doc No

DC-110

Rev. No

2

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

We, the manufacturer, herewith declare that the products

### **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

### DiaFil Flow

(including system components and accessories)

**GMDN** 

35870

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

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# TÜV Rheinland LGA Products GmbH

Tillystraße 2, 90431, Nürnberg, Germany

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## **DiaDent Group International**

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

2020-06-01

DiaDent Group International

Date

**DiaDent Group International** 

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

Tel: 82-43-266-2315

Fax: 82-43-262-8658 E-mail: diadent@diadent co kr



http://www.diadent.co.kr



Doc No

DC-111

Rev.No

2

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

DiaDent Europe B.V.

**Authorized Representative:** 

Antennestraat 70, 1322AS Almere, the Netherlands

We, the manufacturer, herewith declare that the products

### **Dia Etch**

(including system components and accessories)

**GMDN** 

36153

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

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

e 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

Signature

DiaDent Group International

16, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea Tel: 82-43-266-2315 Fax: 82-43-262-8658

http://www.diadent.co.kr





Doc No

DC-112

Rev.No

2

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu, Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

We, the manufacturer, herewith declare that the products

### **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

## Dia Plus

**GMDN** 

34782

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

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

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

DiaDent Group Internationa.

Date

Certified 150 13485



**DiaDent Group International** 

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

Tel: 82-43-266-2315 http://www.diadent.co.kr



Doc No :

DC-115

Rev.No

0

#### Manufacturer:

DiaDent Group International

16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu,

Cheongju-si, Chungcheongbuk-do,

28161, Republic of Korea

TOPO TOPO

**Authorized Representative:** 

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

We, the manufacturer, herewith declare that the products

# **D-LUX+(Dental Curing Light)**

(including system components and accessories)

**GMDN** 

35775

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 ClassI(Rule 12) according to Annex IX of the Medical Devices Directive 93/42/EEC amended by 2007/47/EC. It bears the mark

C € 0197

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

DI/A

Issue date

N/A N/A

Expiry date

N/A

following the procedure relating to the EC Declaration of Conformity set out in Annex VIIof
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

DiaDent Group Internati

Signature

Date

16. Osongsaengmyeong 4-ro. Osong-eup, Heungdeok-gu Cheongju-si, Chungcheong buk-do, 28161, Koles

Tel: 8DiaDent 2 Group anternational 58

CE Certified 50 13485

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

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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

We, the manufacturer, herewith declare that the products

## **Authorized Representative:**

DiaDent Europe B.V.

Antennestraat 70, 1322AS Almere, the Netherlands

# 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 Vof 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, Chungcheong buk-do. 2816 Tel: 82-43-266-2315

**DiaDent Group International** 

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

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