EC Declaration of Conformity

Doc No : DC-076(R)
Rev.No : 08

Manufacturer :
DiaDent Group International
16, Osongsaengmyeong 4-ro Osong-eup Heungdeok-gu,

Authorized Representative :
DiaDent Europe B.V.
Antennestraat 70, 1322AS Almere, the Netherlands

We, the manufacturer, herewith declare that the products

e-Temp

(Attachment 1. Model list)

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

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(DIADE_CL607_2024-05-14)
Issue date : 2024-05-14
Expiry date : 2028-12-31

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

2025-11-05

Date

KabSun Lee
/ PRRC of DiaDent Group International

Attachment 1. Model list **DoC No. : DC-076(R)_Rev.08**

Product name or Trade Name	Model Name
e-Temp	e-Temp 30g
	e-Temp 10g
caviDent	Cavident 30g