DiaDent®

EC Declaration of Conformity

Doc No : DC-001(R)
Rev.No : 11

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

Gutta Percha Points

(Brand Name: ENDO STAR
Attachment 1. Model list)

GMDN : 45081

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 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(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 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

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2025-09-22
Date

KabSun Lee
/ PRRC of DiaDent Group International

Attachment 1. Model list

DoC No. : DC-001(R)_Rev.11

Product name or Trade Name	POLDENT Brand Name : Endostar Model Name	DiaDent Group International Brand Name : DIADENT Model Name
Gutta Percha Points	Gutta Percha Points Taper.02 #15	MM MARKED GUTTA PERCHA POINTS ISO #15
	Gutta Percha Points Taper.02 #20	MM MARKED GUTTA PERCHA POINTS ISO #20
	Gutta Percha Points Taper.02 #25	MM MARKED GUTTA PERCHA POINTS ISO #25
	Gutta Percha Points Taper.02 #30	MM MARKED GUTTA PERCHA POINTS ISO #30
	Gutta Percha Points Taper.02 #35	MM MARKED GUTTA PERCHA POINTS ISO #35
	Gutta Percha Points Taper.02 #40	MM MARKED GUTTA PERCHA POINTS ISO #40
	Gutta Percha Points Taper.02 #45	MM MARKED GUTTA PERCHA POINTS ISO #45
	Gutta Percha Points Taper.02 #50	MM MARKED GUTTA PERCHA POINTS ISO #50
	Gutta Percha Points Taper.02 #55	MM MARKED GUTTA PERCHA POINTS ISO #55
	Gutta Percha Points Taper.02 #60	MM MARKED GUTTA PERCHA POINTS ISO #60
	Gutta Percha Points Taper.02 #70	MM MARKED GUTTA PERCHA POINTS ISO #70
	Gutta Percha Points Taper.02 #80	MM MARKED GUTTA PERCHA POINTS ISO #80
	Gutta Percha Points Taper.02 #15/40	MM MARKED GUTTA PERCHA POINTS ISO #15/40
	Gutta Percha Points Taper.02 #45/80	MM MARKED GUTTA PERCHA POINTS ISO #45/80
	Gutta Percha Points Taper.04 #15	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #15
	Gutta Percha Points Taper.04 #20	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #20
	Gutta Percha Points Taper.04 #25	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #25
	Gutta Percha Points Taper.04 #30	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #30
	Gutta Percha Points Taper.04 #35	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #35
	Gutta Percha Points Taper.04 #40	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #40
	Gutta Percha Points Taper.04 #45	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #45
	Gutta Percha Points Taper.04 #50	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #50
	Gutta Percha Points Taper.04 #55	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #55
	Gutta Percha Points Taper.04 #60	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #60
	Gutta Percha Points Taper.04 #70	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #70
	Gutta Percha Points Taper.04 #80	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #80
	Gutta Percha Points Taper.04 #15/40	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #15/40
	Gutta Percha Points Taper.04 #45/80	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.04 PLUS #45/80
	Gutta Percha Points Taper.06 #15	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #15
	Gutta Percha Points Taper.06 #20	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #20
	Gutta Percha Points Taper.06 #25	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #25
	Gutta Percha Points Taper.06 #30	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #30
	Gutta Percha Points Taper.06 #35	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #35
	Gutta Percha Points Taper.06 #40	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #40
	Gutta Percha Points Taper.06 #45	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #45
	Gutta Percha Points Taper.06 #50	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #50
	Gutta Percha Points Taper.06 #55	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #55
	Gutta Percha Points Taper.06 #60	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #60
	Gutta Percha Points Taper.06 #70	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #70
	Gutta Percha Points Taper.06 #80	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #80
	Gutta Percha Points Taper.06 #15/40	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #15/40
	Gutta Percha Points Taper.06 #45/80	MM MARKED GUTTA PERCHA POINTS DIA-PROISO.06 PLUS #45/80

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