

EC Declaration of Conformity

**according to the Medical Devices Directive 93/42/EEC
as amended by Directive 2007/47/EC**

For the following medical device :

Product name : Gutta Percha Points

Brand name: Gutta Percha Points and Bars (detailed model names attached)

Classification : Class IIa by Rule 8 of Annex IX, Council Directive 93/42/EEC as amended by Directive 2007/47/EC

Manufacturer's Name : META BIOMED CO., LTD.

Manufacturer's Address : 270, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu,
Cheongju-si, Chungcheongbuk-do, Korea

is herewith the conformity with the requirements set out in the Council Directive 93/42/EEC of 14 June 1993 as amended by Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 concerning Medical Devices declared, For the evaluation of the conformity with this Directive, the following standards have been applied:

MDD 93/42/EEC, MEDDEV 2.12-1 Rev.8, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12.2 Rev.2, EN ISO 13485:2016, FDA 21 CFR 820, EN ISO 14971:2019, ISO/TR 24971:2020, EN 1041:2008, EN ISO 15223-1:2016, EN 1641:2009, EN ISO 6877:2021, ANSI/ADA 78-2006, EN ISO 7405:2018, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-23:2021, EN ISO 14644-1:2015, EN ISO 14644-2:2015, EN ISO 14644-3:2019, EN ISO 14644-4:2022, EN ISO 14644-5:2004, EN ISO 14644-7:2004, EN ISO 14644-8:2022, EN ISO 14644-9:2022, EN ISO 14644-10:2022, ISO 14644-12:2018, EN ISO 14644-13:2017, EN ISO 14644-14:2016, EN ISO 14644-15:2017, EN ISO 14644-16:2019, EN ISO 14644-17:2021, EN ISO 14698-1:2003, EN ISO 14698-2:2003, BS EN 17141:2020, KS A 3011:2018, USP <1116>, ASTM F1980-21, ISTA 1A 2022, EN 62366-1:2015, IEC TR 62366-2:2016, ISO/TR 20416:2020

is subject to the procedure set out in Annex II (excluding section 4) of Directive 93/42/EEC under the supervision of Notified Body Number 1639, SGS Belgium NV, Noorderlaan 87, BE-2030 Antwerpen, Belgium.

GMDN Code : 45081(Synthetic gutta-percha)

EC Certificate Number : KR19/81826259

Responsible for making this declaration is the :

■ Manufacturer: META BIOMED CO., LTD.

European Representative is:

■ Meta Biomed Europe GmbH, Wiesenstr. 35, 45473 Mülheim an der Ruhr, Germany

■ Tel: +49-208-30991910, Fax: +49-208-30991999

We, the manufacturer's declaration, declare and ensure with sole responsibility, that the Medical Device meet the provisions of Council Directive 93/42/EEC (Medical Device Directive) which apply to them

Person responsible for making this declaration:

Name, Surname : Suk Song Oh

Position/Title : PRESIDENT



Place: Cheongju-si **Date:** November 08, 2023

(Company stamp and legal signature)

(Attachment: Model name list)

Brand Name	Model Name					
Gutta Percha Points and Bars	1	Gutta Percha 02-10	41	Gutta Percha 06-50	81	Gutta Percha 04-LM-55
	2	Gutta Percha 02-15	42	Gutta Percha 06-55	82	Gutta Percha 04-LM-60
	3	Gutta Percha 02-20	43	Gutta Percha 06-60	83	Gutta Percha 04-LM-70
	4	Gutta Percha 02-25	44	Gutta Percha 06-70	84	Gutta Percha 04-LM-80
	5	Gutta Percha 02-30	45	Gutta Percha 06-80	85	Gutta Percha 06-LM-10
	6	Gutta Percha 02-35	46	Gutta Percha 08-10	86	Gutta Percha 06-LM-15
	7	Gutta Percha 02-40	47	Gutta Percha 08-15	87	Gutta Percha 06-LM-20
	8	Gutta Percha 02-45	48	Gutta Percha 08-20	88	Gutta Percha 06-LM-25
	9	Gutta Percha 02-50	49	Gutta Percha 08-25	89	Gutta Percha 06-LM-30
	10	Gutta Percha 02-55	50	Gutta Percha 08-30	90	Gutta Percha 06-LM-35
	11	Gutta Percha 02-60	51	Gutta Percha 08-35	91	Gutta Percha 06-LM-40
	12	Gutta Percha 02-70	52	Gutta Percha 08-40	92	Gutta Percha 06-LM-45
	13	Gutta Percha 02-80	53	Gutta Percha 02-LM-10	93	Gutta Percha 06-LM-50
	14	Gutta Percha 02-90	54	Gutta Percha 02-LM-15	94	Gutta Percha 06-LM-55
	15	Gutta Percha 02-100	55	Gutta Percha 02-LM-20	95	Gutta Percha 06-LM-60
	16	Gutta Percha 02-110	56	Gutta Percha 02-LM-25	96	Gutta Percha 06-LM-70
	17	Gutta Percha 02-120	57	Gutta Percha 02-LM-30	97	Gutta Percha 06-LM-80
	18	Gutta Percha 02-130	58	Gutta Percha 02-LM-35	98	Gutta Percha 08-LM-10
	19	Gutta Percha 02-140	59	Gutta Percha 02-LM-40	99	Gutta Percha 08-LM-15
	20	Gutta Percha 04-10	60	Gutta Percha 02-LM-45	100	Gutta Percha 08-LM-20
	21	Gutta Percha 04-15	61	Gutta Percha 02-LM-50	101	Gutta Percha 08-LM-25
	22	Gutta Percha 04-20	62	Gutta Percha 02-LM-55	102	Gutta Percha 08-LM-30
	23	Gutta Percha 04-25	63	Gutta Percha 02-LM-60	103	Gutta Percha 08-LM-35
	24	Gutta Percha 04-30	64	Gutta Percha 02-LM-70	104	Gutta Percha 08-LM-40
	25	Gutta Percha 04-35	65	Gutta Percha 02-LM-80	105	Gutta Percha R-XF
	26	Gutta Percha 04-40	66	Gutta Percha 02-LM-90	106	Gutta Percha R-FF
	27	Gutta Percha 04-45	67	Gutta Percha 02-LM-100	107	Gutta Percha R-MF
	28	Gutta Percha 04-50	68	Gutta Percha 02-LM-110	108	Gutta Percha R-M
	29	Gutta Percha 04-55	69	Gutta Percha 02-LM-120	109	Gutta Percha R-F
	30	Gutta Percha 04-60	70	Gutta Percha 02-LM-130	110	Gutta Percha R-FM
	31	Gutta Percha 04-70	71	Gutta Percha 02-LM-140	111	Gutta Percha R-ML
	32	Gutta Percha 04-80	72	Gutta Percha 04-LM-10	112	Gutta Percha R-L
	33	Gutta Percha 06-10	73	Gutta Percha 04-LM-15	113	Gutta Percha R-XL
	34	Gutta Percha 06-15	74	Gutta Percha 04-LM-20	114	Gutta Percha LM-R-XF
	35	Gutta Percha 06-20	75	Gutta Percha 04-LM-25	115	Gutta Percha LM-R-FF
	36	Gutta Percha 06-25	76	Gutta Percha 04-LM-30	116	Gutta Percha LM-R-MF
	37	Gutta Percha 06-30	77	Gutta Percha 04-LM-35	117	Gutta Percha LM-R-M
	38	Gutta Percha 06-35	78	Gutta Percha 04-LM-40	118	Gutta Percha LM-R-F
	39	Gutta Percha 06-40	79	Gutta Percha 04-LM-45	119	Gutta Percha LM-R-FM
	40	Gutta Percha 06-45	80	Gutta Percha 04-LM-50	120	Gutta Percha LM-R-ML

Brand Name	Model Name					
Gutta Percha Points and Bars	121	Gutta Percha LM-R-L	161	Gutta Percha KG AF 06	201	Gutta Percha J/S/J-FS/J-FM/J-FL
	122	Gutta Percha LM-R-XL	162	Gutta Percha SG AB F	202	Gutta percha R-XF/R-M
	123	Gutta Percha F-XF	163	Gutta Percha SG AB FM	203	Gutta percha R-F/R-ML
	124	Gutta Percha F-FF	164	Gutta Percha SG AB M	204	Gutta Percha D-XXF/D-M
	125	Gutta Percha F-MF	165	Gutta Percha SG AB ML		
	126	Gutta Percha F-M	166	Gutta Percha SG AF FF		
	127	Gutta Percha F-F	167	Gutta Percha SG AF MF		
	128	Gutta Percha F-FM	168	Gutta Percha SG AF F		
	129	Gutta Percha F-ML	169	Gutta Percha SG AF FM		
	130	Gutta Percha F-L	170	Gutta Percha SG AF M		
	131	Gutta Percha F-XL	171	Gutta Percha SG AF ML		
	132	Gutta Percha J-FS	172	Gutta Percha SG AF L		
	133	Gutta Percha J-FM	173	Gutta Percha F1		
	134	Gutta Percha J-FL	174	Gutta Percha F2		
	135	Gutta Percha J-S	175	Gutta Percha F3		
	136	Gutta Percha J-M	176	Gutta Percha F4		
	137	Gutta Percha J-L	177	Gutta Percha F5		
	138	Gutta Percha J-LM	178	Gutta Percha LM F1		
	139	Gutta Percha J-XL	179	Gutta Percha LM F2		
	140	Gutta Percha D-XXF	180	Gutta Percha LM F3		
	141	Gutta Percha D-XF	181	Gutta Percha LM F4		
	142	Gutta Percha D-F	182	Gutta Percha LM F5		
	143	Gutta Percha D-M	183	Gutta percha 02-15/40		
	144	Gutta Percha D-XL	184	Gutta percha 02-45/80		
	145	Gutta Percha TF 04-25	185	Gutta percha 04-15/40		
	146	Gutta Percha TF 06-30	186	Gutta percha 04-45/80		
	147	Gutta Percha TF 06-35	187	Gutta percha 06-15/40		
	148	Gutta Percha TF 04-40	188	Gutta percha 06-45/80		
	149	Gutta Percha TF 04-50	189	Gutta percha 08-15/40		
	150	Gutta Percha TF 06-25	190	Gutta percha 02-LM-15/40		
	151	Gutta Percha TF 08-25	191	Gutta percha 02-LM-45/80		
	152	Gutta Percha TF 10-25	192	Gutta percha 04-LM-15/40		
	153	Gutta Percha TF 12-25-S	193	Gutta percha 04-LM-45/80		
	154	Gutta Percha SG AT 04	194	Gutta percha 06-LM-15/40		
	155	Gutta Percha SG AT 06	195	Gutta percha 06-LM-45/80		
	156	Gutta Percha SG AT 08	196	Gutta percha 08-LM-15/40		
	157	Gutta Percha SG AT 10	197	Gutta percha F1/F2/F3		
	158	Gutta Percha SG AT 12-L	198	Gutta percha LM F1/F2/F3		
	159	Gutta Percha SG AT 12-S	199	Gutta Percha 02-90/140		
	160	Gutta Percha KG AF 04	200	Gutta Percha 02-LM-90/140		