

EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

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, Osongsaengmyeong1-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 2.12.2 Rev.2, MEDDEV 2.7.1 Rev.4, EN 1641:2009, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2009, EN ISO 7405:2018, ISO 6877:2006, EN 1041:2008, EN 15223-1:2016, EN ISO 13485:2016, EN ISO 14971:2012

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

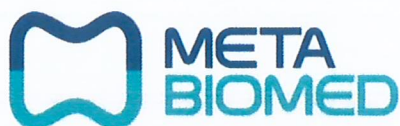
Position/Title : PRESIDENT



Place: Cheongju-si

Date: February 2nd, 2021

(Company stamp and legal signature)



META BIOMED CO., LTD.

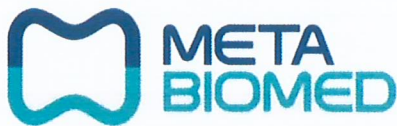
Osong factory): 270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, Korea

T) +82-43-216-0433 F) +82-43-217-1988

Email: info@meta-biomed.com Home Page: www.meta-biomed.com

(Attachment: Model name list)

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



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Brand Name	Model Name					
Gutta Percha Points and Bars	121	Gutta Percha 02-LM-40	161	Gutta Percha 06-LM-50	201	Gutta Percha 10-LM-60
	122	Gutta Percha 02-LM-45	162	Gutta Percha 06-LM-55	202	Gutta Percha 10-LM-70
	123	Gutta Percha 02-LM-50	163	Gutta Percha 06-LM-60	203	Gutta Percha 10-LM-80
	124	Gutta Percha 02-LM-55	164	Gutta Percha 06-LM-70	204	Gutta Percha 10-LM-90
	125	Gutta Percha 02-LM-60	165	Gutta Percha 06-LM-80	205	Gutta Percha 10-LM-100
	126	Gutta Percha 02-LM-70	166	Gutta Percha 06-LM-90	206	Gutta Percha 10-LM-110
	127	Gutta Percha 02-LM-80	167	Gutta Percha 06-LM-100	207	Gutta Percha 10-LM-120
	128	Gutta Percha 02-LM-90	168	Gutta Percha 06-LM-110	208	Gutta Percha 10-LM-130
	129	Gutta Percha 02-LM-100	169	Gutta Percha 06-LM-120	209	Gutta Percha 10-LM-140
	130	Gutta Percha 02-LM-110	170	Gutta Percha 06-LM-130	210	Gutta Percha 12-LM-10
	131	Gutta Percha 02-LM-120	171	Gutta Percha 06-LM-140	211	Gutta Percha 12-LM-15
	132	Gutta Percha 02-LM-130	172	Gutta Percha 08-LM-10	212	Gutta Percha 12-LM-20
	133	Gutta Percha 02-LM-140	173	Gutta Percha 08-LM-15	213	Gutta Percha 12-LM-25
	134	Gutta Percha 04-LM-10	174	Gutta Percha 08-LM-20	214	Gutta Percha 12-LM-30
	135	Gutta Percha 04-LM-15	175	Gutta Percha 08-LM-25	215	Gutta Percha 12-LM-35
	136	Gutta Percha 04-LM-20	176	Gutta Percha 08-LM-30	216	Gutta Percha 12-LM-40
	137	Gutta Percha 04-LM-25	177	Gutta Percha 08-LM-35	217	Gutta Percha 12-LM-45
	138	Gutta Percha 04-LM-30	178	Gutta Percha 08-LM-40	218	Gutta Percha 12-LM-50
	139	Gutta Percha 04-LM-35	179	Gutta Percha 08-LM-45	219	Gutta Percha 12-LM-55
	140	Gutta Percha 04-LM-40	180	Gutta Percha 08-LM-50	220	Gutta Percha 12-LM-60
	141	Gutta Percha 04-LM-45	181	Gutta Percha 08-LM-55	221	Gutta Percha 12-LM-70
	142	Gutta Percha 04-LM-50	182	Gutta Percha 08-LM-60	222	Gutta Percha 12-LM-80
	143	Gutta Percha 04-LM-55	183	Gutta Percha 08-LM-70	223	Gutta Percha 12-LM-90
	144	Gutta Percha 04-LM-60	184	Gutta Percha 08-LM-80	224	Gutta Percha 12-LM-100
	145	Gutta Percha 04-LM-70	185	Gutta Percha 08-LM-90	225	Gutta Percha 12-LM-110
	146	Gutta Percha 04-LM-80	186	Gutta Percha 08-LM-100	226	Gutta Percha 12-LM-120
	147	Gutta Percha 04-LM-90	187	Gutta Percha 08-LM-110	227	Gutta Percha 12-LM-130
	148	Gutta Percha 04-LM-100	188	Gutta Percha 08-LM-120	228	Gutta Percha 12-LM-140
	149	Gutta Percha 04-LM-110	189	Gutta Percha 08-LM-130	229	Gutta Percha R-XF
	150	Gutta Percha 04-LM-120	190	Gutta Percha 08-LM-140	230	Gutta Percha R-FF
	151	Gutta Percha 04-LM-130	191	Gutta Percha 10-LM-10	231	Gutta Percha R-MF
	152	Gutta Percha 04-LM-140	192	Gutta Percha 10-LM-15	232	Gutta Percha R-M
	153	Gutta Percha 06-LM-10	193	Gutta Percha 10-LM-20	233	Gutta Percha R-F
	154	Gutta Percha 06-LM-15	194	Gutta Percha 10-LM-25	234	Gutta Percha R-FM
	155	Gutta Percha 06-LM-20	195	Gutta Percha 10-LM-30	235	Gutta Percha R-ML
	156	Gutta Percha 06-LM-25	196	Gutta Percha 10-LM-35	236	Gutta Percha R-L
	157	Gutta Percha 06-LM-30	197	Gutta Percha 10-LM-40	237	Gutta Percha R-XL
	158	Gutta Percha 06-LM-35	198	Gutta Percha 10-LM-45	238	Gutta Percha F-XF
	159	Gutta Percha 06-LM-40	199	Gutta Percha 10-LM-50	239	Gutta Percha F-FF
	160	Gutta Percha 06-LM-45	200	Gutta Percha 10-LM-55	240	Gutta Percha F-MF



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Gutta Percha Points and Bars	241	Gutta Percha F-M	281	Gutta Percha TF 12-25-S	321	Gutta percha 04-LM-45/80
	242	Gutta Percha F-F	282	Gutta Percha SG AT 04	322	Gutta percha 06-LM-15/40
	243	Gutta Percha F-FM	283	Gutta Percha SG AT 06	323	Gutta percha 06-LM-45/80
	244	Gutta Percha F-ML	284	Gutta Percha SG AT 08	324	Gutta percha 08-LM-15/40
	245	Gutta Percha F-L	285	Gutta Percha SG AT 10	325	Gutta percha F1/F2/F3
	246	Gutta Percha F-XL	286	Gutta Percha SG AT 12-L	326	Gutta percha LM F1/F2/F3
	247	Gutta Percha J-FS	287	Gutta Percha SG AT 12-S		
	248	Gutta Percha J-FM	288	Gutta Percha KG AF 04		
	249	Gutta Percha J-FL	289	Gutta Percha KG AF 06		
	250	Gutta Percha J-S	290	Gutta Percha SG AB F		
	251	Gutta Percha J-M	291	Gutta Percha SG AB FM		
	252	Gutta Percha J-L	292	Gutta Percha SG AB M		
	253	Gutta Percha J-LM	293	Gutta Percha SG AB ML		
	254	Gutta Percha J-XL	294	Gutta Percha SG AF FF		
	255	Gutta Percha D-XXF	295	Gutta Percha SG AF MF		
	256	Gutta Percha D-XF	296	Gutta Percha SG AF F		
	257	Gutta Percha D-F	297	Gutta Percha SG AF FM		
	258	Gutta Percha D-M	298	Gutta Percha SG AF M		
	259	Gutta Percha D-XL	299	Gutta Percha SG AF ML		
	260	Gutta Percha GC-FL	300	Gutta Percha SG AF L		
	261	Gutta Percha GC-L	301	Gutta Percha F1		
	262	Gutta Percha GC-LL	302	Gutta Percha F2		
	263	Gutta Percha GC-XL	303	Gutta Percha F3		
	264	Gutta Percha GC-FS	304	Gutta Percha F4		
	265	Gutta Percha GC-S	305	Gutta Percha F5		
	266	Gutta Percha GC-LS	306	Gutta Percha LM F1		
	267	Gutta Percha GC-FM	307	Gutta Percha LM F2		
	268	Gutta Percha GC-M	308	Gutta Percha LM F3		
	269	Gutta Percha GC-LM	309	Gutta Percha LM F4		
	270	Gutta Percha ALPHA	310	Gutta Percha LM F5		
	271	Gutta Percha BETA	311	Gutta percha 02-15/40		
	272	Gutta Percha GP-BAR	312	Gutta percha 02-45/80		
	273	Gutta Percha TF 04-25	313	Gutta percha 04-15/40		
	274	Gutta Percha TF 06-30	314	Gutta percha 04-45/80		
	275	Gutta Percha TF 06-35	315	Gutta percha 06-15/40		
	276	Gutta Percha TF 04-40	316	Gutta percha 06-45/80		
	277	Gutta Percha TF 04-50	317	Gutta percha 08-15/40		
	278	Gutta Percha TF 06-25	318	Gutta percha 02-LM-15/40		
	279	Gutta Percha TF 08-25	319	Gutta percha 02-LM-45/80		
	280	Gutta Percha TF 10-25	320	Gutta percha 04-LM-15/40		