META BIOMED CO., LTD.
270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
T) +82-43-216-0433 F) +82-43-217-1988
Email: info@meta-biomed.com Home Page: www.meta-biomed.com

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: Sterile Absorbent Paper Points

Brand name : Absorbent Paper Points (detailed model names attached)

Classification : Class IIa by Rule 6 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:

FDA 21 CFR 820, EN ISO 13485:2016, EN ISO 14971:2019, ISO/TR 24971:2020, EN 1041:2008, EN ISO 15223-1:2021, MEDDEV 2.12-1 Rev.8, MEDDEV 2.7.1 Rev.4, MEDDEV 2.12.2 Rev.2, EN ISO 7551:2023, ADA/ANSI 73:1993, EN ISO 7405:2018, EN ISO 10993-1:2020, EN ISO 10993-3:2014, EN ISO 10993-5:2009, EN ISO 10993-6:2016, EN ISO 10993-10:2023, EN ISO 10993-11:2018, EN ISO 10993-12:2021, EN ISO 10993-23:2021, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11137-3:2017, EN 556-1:2001, ASTM F1980-21, 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>, EN ISO 11607-1:2020, EN ISO 11607-2:2020, ASTM F88/F88M:2015, ASTM F1929:2015, EN ISO 11737-1:2018, EN ISO 11737-2:2020, 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 : 38777 (Endodontic paper point)
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**

Suk Song Oh
(Company stamp and legal signature)

META BIOMED CO., LTD.
270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 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					
Absorbent Paper Points	1	10	41	06-50	81	Length Marked 120
	2	15	42	06-55	82	Length Marked 130
	3	20	43	06-60	83	Length Marked 140
	4	25	44	06-70	84	Length Marked 04-10
	5	30	45	06-80	85	Length Marked 04-15
	6	35	46	08-10	86	Length Marked 04-20
	7	40	47	08-15	87	Length Marked 04-25
	8	45	48	08-20	88	Length Marked 04-30
	9	50	49	08-25	89	Length Marked 04-35
	10	55	50	08-30	90	Length Marked 04-40
	11	60	51	08-35	91	Length Marked 04-45
	12	70	52	08-40	92	Length Marked 04-50
	13	80	53	B-XXF	93	Length Marked 04-55
	14	90	54	B-XF	94	Length Marked 04-60
	15	100	55	B-F	95	Length Marked 04-70
	16	110	56	B-M	96	Length Marked 04-80
	17	120	57	B-C	97	Length Marked 06-10
	18	130	58	B-XC	98	Length Marked 06-15
	19	140	59	LM-B-XXF	99	Length Marked 06-20
	20	04-10	60	LM-B-XF	100	Length Marked 06-25
	21	04-15	61	LM-B-F	101	Length Marked 06-30
	22	04-20	62	LM-B-M	102	Length Marked 06-35
	23	04-25	63	LM-B-C	103	Length Marked 06-40
	24	04-30	64	LM-B-XC	104	Length Marked 06-45
	25	04-35	65	Length Marked 10	105	Length Marked 06-50
	26	04-40	66	Length Marked 15	106	Length Marked 06-55
	27	04-45	67	Length Marked 20	107	Length Marked 06-60
	28	04-50	68	Length Marked 25	108	Length Marked 06-70
	29	04-55	69	Length Marked 30	109	Length Marked 06-80
	30	04-60	70	Length Marked 35	110	Length Marked 08-10
	31	04-70	71	Length Marked 40	111	Length Marked 08-15
	32	04-80	72	Length Marked 45	112	Length Marked 08-20
	33	06-10	73	Length Marked 50	113	Length Marked 08-25
	34	06-15	74	Length Marked 55	114	Length Marked 08-30
	35	06-20	75	Length Marked 60	115	Length Marked 08-35
	36	06-25	76	Length Marked 70	116	Length Marked 08-40
	37	06-30	77	Length Marked 80	117	PP F1
	38	06-35	78	Length Marked 90	118	PP F2
	39	06-40	79	Length Marked 100	119	PP F3
	40	06-45	80	Length Marked 110	120	PP F4

META BIOMED CO., LTD.
270, Osongsaengmyeong1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea
T) +82-43-216-0433 F) +82-43-217-1988
Email: info@meta-biomed.com Home Page: www.meta-biomed.com

Brand Name	Model Name			
Absorbent Paper Points	121	PP F5	135	Length Marked 45/80
	122	PP Length Marked F1	136	Length Marked 04-15/40
	123	PP Length Marked F2	137	Length Marked 04-45/80
	124	PP Length Marked F3	138	Length Marked 06-15/40
	125	PP Length Marked F4	139	Length Marked 06-45/80
	126	PP Length Marked F5	140	Length Marked 08-15/40
	127	15/40	141	PP F1/F3
	128	45/80	142	PP Length Marked F1/F3
	129	04-15/40	143	90/140
	130	04-45/80	144	Length Marked 90/140
	131	06-15/40	145	B-XXF/B-XC
	132	06-45/80		
	133	08-15/40		
	134	Length Marked 15/40		