



EU- Declaration of Conformity

Manufacturer : SungKwang Meditech co., ltd (www.skmeditech.com)
1024-20, Bukhansan-ro, Jangheung-myeon,
Yangju-si, Gyeonggi-do, South Korea
skmeditech@skmeditech.com / 82-10-4590-7548

European Authorized Representative
(Article 2(32) of the MDR 2017/745) : ORMEDAN S.L. (www.normedan.com)
Polígono Plazaola, Manzana F, 2º C
31195 Aizoain (Navarra) SPAIN
paco.ramos@normedan.com / 34 902 260793

Conformity Assessment Route: *Annex II & III & IV Medical Device Regulation (MDR) 2017/745*
(Article 52 of the MDR 2017/745)

Classification (MDR, Annex VIII): *Class I, Rule 1*
Trade Name: *Gel Pad*
Brand Name: *SK Gel Pad*
Model Name: *Appendix*
Intended Purpose: *To provide pressure relief and constant support*

This declaration of conformity is issued under the sole responsibility of SungKwang Meditech co., ltd.
We hereby declare that the medical device(s) specified above meet the provisions of the EU Medical Device Regulation (MDR) 2017/745. These devices are in conformity to the MDR 2017/745 that provides for the issuing of the EU Declaration of Conformity (DOC). All supporting documentation is retained at the premises of the manufacturer.

Signature:

**Jung Ae Lee,
President**

Place and Date(dd/mm/yyyy) of issue:

Manufacturer's place and 26/05/2021

Appendix- Model Name and basic UDI-DI ;

No.	Model Name	UDI-DI	No.	Model Name	UDI-DI
1	SK-22	08809240020555	39	SK-27-3	08809240020913
2	SK-22-3	08809240020616	40	SK-27-4	08809240020920
3	SK-22-4	08809240020623	41	SK-27-a	08809240020838
4	SK-22-1	08809240020562	42	SK-27-b	08809240020845
5	SK-22-1-1	08809240020579	43	SK-27-c	08809240020852
6	SK-22-1-2	08809240020586	44	SK-27-d	08809240020869
7	SK-22-a	08809240020630	45	SK-27-e	08809240020876
8	SK-22-b	08809240020647	46	SK-28	08809240020937
9	SK-22-c	08809240020654	47	SK-28-1	08809240020944
10	SK-22-d	08809240020661	48	SK-28-2	08809240020951
11	SK-22-e	08809240020678	49	SK-28-3	08809240020968
12	SK-22-5	08809240029077	50	SK-29	08809240020975
13	SK-22-2	08809240020593	51	SK-29-1	08809240020517
14	SK-22-2-1	08809240020609	52	SK-29-1a	08809240020524
15	SK-23	08809240020685	53	SK-17-a	08809240020531
16	SK-23-1	08809240020692	54	SK-17-b	08809240020548
17	SK-23-2	08809240029060	55	SK-17-c	08809240028810
18	SK-23-1-1	08809240020708	56	SK-17-1	08809240020432
19	SK-23-1-1a	08809240020715	57	SK-5-1a	08809240028827
20	SK-23-1-1b	08809240020722	58	SK-17-1-1	08809240020449
21	SK-23-1-1c	08809240020739	59	SK-17-2	08809240020456
22	SK-23-5	08809240020005	60	SK-17-2-1	08809240020463
23	SK-23-5-1	08809240020302	61	SK-17-3	08809240020470
24	SK-24	08809240020746	62	SK-17-3-1	08809240020487
25	SK-24-2	08809240020760	63	SK-17-4-1	08809240020494
26	SK-24-2-1	08809240020777	64	SK-17-5	08809240020500
27	SK-24-2-2	08809240020784	65	SK-17-6	08809240028834
28	SK-24-3	08809240020791	66	SK-17-6-1	08809240028841
29	SK-24-1	08809240020753	67	SK-17-6-2	08809240028858
30	SK-23-4	08809240020326	68	SK-22-1X	08809240028957
31	SK-23-3	08809240020319	69	RH-1	08809240020265
32	SK-25	08809240020807	70	RH-2	08809240020272
33	SK-25-1	08809240020814	71	RH-3	08809240020289
34	SK-26	08809240020821	72	RH-4	08809240020296
35	SK-26-2	08809240028803	73	RH-6	08809240020333
36	SK-27	08809240020883	74	RH-6-1	08809240020364
37	SK-27-1	08809240020890	75	SK-eq-a	08809240020371
38	SK-27-2	08809240020906	76	SK-eq-b	08809240020388