



# Statement of Compliance

This is to state that Technical Documentation TCF, Rev.0 for Gel Pad

*Gel Pad (SK Gel Pad)*

*See the next pages for model names*

*(Annex I and relevant provision of Directive 93/42/EEC as amended by 2007/47/EC)*

*Manufactured by*

**SUNGKWANG MEDITECH COMPANY**  
**#322-5 Eungam-Ro Eunpyeong-Gu, Seoul, South Korea**

*Has been assessed as meeting the Essential Requirements and relevant provisions of EC Directive 93/42/EEC as amended by 2007/47 for Medical Devices*

For SGS Korea Co., Ltd.  
System & Services Certification Division

Date of review: 2014-01-23  
Reference No: CE/1401



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While all due care and skill was exercised in carrying out this assessment, SGS Korea accepts responsibility only for proven gross negligence. This certificate relates only to the medical device as described in the technical file reviewed on the date shown. Conformance to all the regulatory requirements is the sole responsibility of the manufacturer including the manufacture and quality control of the products. This is not a legal document and cannot be used as such. This certificate remains the property of SGS Korea Ltd. to whom it must be returned on request.

***Gel Pad (SK Gel Pad)***

<b>No.</b>	<b>Model Name</b>	<b>No.</b>	<b>Model Name</b>	<b>No.</b>	<b>Model Name</b>
1	SK-22	23	SK-24-2	45	SK-28-1
2	SK-22-3	24	SK-24-2-1	46	SK-28-2
3	SK-22-4	25	SK-24-2-2	47	SK-28-3
4	SK-22-1	26	SK-24-3	48	SK-29
5	SK-22-1-1	27	SK-24-1	49	SK-29-1
6	SK-22-1-2	28	SK-23-4	50	SK-29-1a
7	SK-22-a	29	SK-23-3	51	SK-17-a
8	SK-22-b	30	SK-25	52	SK-17-b
9	SK-22-c	31	SK-25-1	53	SK-17-c
10	SK-22-d	32	SK-26	54	SK-5-1a
11	SK-22-e	33	SK-26-2	55	SK-17-1
12	SK-22-2	34	SK-27	56	SK-17-1-1
13	SK-23	35	SK-27-1	57	SK-17-2
14	SK-23-1	36	SK-27-2	58	SK-17-2-1
15	SK-23-2	37	SK-27-3	59	SK-17-3
16	SK-23-1-1	38	SK-27-4	60	SK-17-3-1
17	SK-23-1-1a	39	SK-27-a	61	SK-17-4-1
18	SK-23-1-1b	40	SK-27-b	62	SK-17-5
19	SK-23-1-1c	41	SK-27-c	63	SK-17-6
20	SK-23-5	42	SK-27-d	64	SK-17-6-1
21	SK-23-5-1	43	SK-27-e	65	SK-17-6-2
22	SK-24	44	SK-28		