



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Jiangsu Saikang Medical Equipment Co., Ltd.
Address: No. 35 Lehong Road, Modern Agriculture Demonstration Park, Zhangjiagang City, Jiangsu Province, China
EC Representative: SUNGO Europe B.V.
Address: Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247
Product Name: Operating Lamp
Model/Size: See Annex
EMDN: Z120107

SRN: CN-MF-000002228 **Basic UDI-DI:** 697453996OperatingLampVC

Classification: Class I
Rule: Rule 13, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2019	EN ISO 15223-1: 2021
EN ISO 20417:2021	EN 60601-1:2006+A2:2020
EN 60601-1-2:2015+A1:2020	EN 60601-2-41:2015

Signature: Bessie WANG
Position: GM
Date: Jan. 11th, 2023
Place: Jiangsu / China

江苏赛康医疗设备股份有限公司
JIANGSU SAIKANG MEDICAL EQUIPMENT CO., LTD.

Annex

SK-L201	SK-L202	SK-L204	SK-L205	SK-L206	SK-L207
SK-L208	SK-L210	SK-L212	SK-L213	SK-L260	SK-L261
SK-L262	SK-L274	SK-L275	SK-L276	SK-L226	SK-L278
SK-L227	SK-L275-M	SK-L203	SK-L323	SK-L316	SK-L317
SK-L318	SK-L319	SK-L320	SK-L321	SK-L322	SK-L325
SK-L326	SK-L326A	SK-L271	SK-L301	SK-L302	SK-L303
SK-L304	SK-L305	SK-L279	SK-L280	SK-L281	SK-L228
SK-L324	SK-L329	SK-L332	SK-L331	SK-L330	SK-L340
SK-L341	SK-L342	SK-L343	SK-L344	SK-L345	SK-L346
SK-L346A	SK-L347	SK-L348	SK-L349	SK-L350	SK-L351
SK-L352	SK-L353	SK-L353A	SK-L354	SK-L355	SK-L356
SK-L329-M	SK-L357	SK-L380	SK-L358	SK-L601	SK-L420
SK-L421	SK-L443	SK-L440	SK-L604	SK-L277	SK-L214
SK-L215	SK-L216	SK-L220	SK-L410	SK-L413	SK-L414
SK-L602	SK-L305-1	SK-L603	SK-L605	SK-LKD05A	SK-LKD09A
SK-LKD12A	SK-LKD1205A	SK-LKY04A	SK-LKY05A	SK-LZD50A	SK-LZD70A
SK-LZD7050A	SK-LZD7070A	SK-LZY50A	SK-LZY70A	SK-LLD50A	SK-LLD70A
SK-LLD7070A	SK-LLD7050A	SK-LLY50A	SK-LLY70A	SK-LLD7070B	SK-LLD7050B
SK-LLY70B	SK-LLD50B	SK-LLD70B	SK-LLY50B	SK-LLD7272C	SK-LLD7252C
SK-LLD72C	SK-LLD52C	SK-LLY72C	SK-LLY52C	SK-LLD0505A	SK-LLD05A
SK-LLY05A	SK-LLD0404B	SK-LLD04B	SK-LLY04B	SK-LLD0505C	SK-LLD05C
SK-LLY05C	SK-LLY03C	SK-LLD0404D	SK-LLD0303D	SK-LLD04D	SK-LLD03D
SK-LLD0503E	SK-LLD05E	SK-LLD03E	SK-LLY03E	SK-LLD7070F	SK-LLD7050F
SK-L410(1)	SK-LLD05D	SK-L401	SK-L402	SK-L221	SK-L222
SK-L223	SK-L217	SK-L218	SK-L219	SK-L312	SK-L313
SK-L008	SK-L010	SK-L011	SK-L012	SK-L013	SK-L014
SK-L015	SK-L016	SK-L017	SK-L018	SK-L314	SK-L315
SK-L315A	SK-L403	SK-L404	SK-L405	SK-L406	SK-L407
SK-L408	SK-L327	SK-L328	SK-L364	SK-L366	SK-LLD0403D
SK-L002A	SK-L023	SK-L024	SK-L333	SK-L282	SK-L283
SK-L284	SK-L285	SK-L286	SK-L287	SK-L287A	SK-L288
SK-L288A	SDL-C0226-2	SK-L025	SK-L423	SK-L422	SK-L411
SK-L412	SK-L424	SK-L367	SK-L368	SK-L441	SK-L442
SK-L306	SK-L001	SK-L002	SK-L224	SK-L225	SK-L006
SK-L009	SK-L020	SK-L026	SK-L027	SK-LED180	SK-L005
SK-L022	SK-L003	SK-L004	SK-L307	SK-L308	SK-L314A
SK-L309	SK-L024	SK-L310	SK-L311	SKH041(6)	SK-LD30
SK-LD60	SK-LD200	SK-LD300	SK-LD450	SK-LY30	SK-LY60

SK-LY200

SK-LY300

SK-LY450

SK-LQ30

SK-LQ60

SK-LQ200

SK-LQ300

SK-LQ450