



# DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



**Manufacturer:** Jianguo 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:** Medical Chair  
**Model/Size:** Refer to Annex

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

**Classification:** Class I  
**Rule:** Rule 1, 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: 2016
EN 1041:2008+A1:2013	ISO 10993-1: 2018
EN ISO 10993-5: 2009	EN ISO 10993-10: 2013

Signature: Bessie WANG

Position: GM

Date: Mar. 11, 2015

Place: Jiangsu / China

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

江苏赛康医疗  
JIANGSU SAIKANG

Annex  
 江苏赛康医疗设备有限公司  
 JIANGSU SANKANG MEDICAL EQUIPMENT CO., LTD.

SKE001	SKE001-3	SKE001-4	SKE014-5	SKE824	SKE-120B
SKE-120A	SKE-180	SKE-170A	SKE-100A	SKE087	SKE091
SKE090	SKE004-1	SKE005	SKE008-1	SKE008	SKE006-1
SKE006-2	SKE802	SKE015-2	SKE801	SKE015-5	SKE013
SKE015-4	SKE013-11	SKE013-10	SKE017-4	SKE702	SKE055-8
SKE031	SKE053-2	SKE052	SKE711	SKE712	SKE088
SKE054-9	SKE055-6	SKE054-5	SKE581	SKE568	SKE163
SKE014-2	SKE014-3	SKE019-2	SKE066	SKE048	SKE055-2
SKE704	SKE705	SKE706	SKE7010	SKE063	SKE001-7
SKE804	SKE001-4-P	SKE059	SKZ705	SKE701	SKE703
SKE013-3	SKE008-109	SKE069	SKE017-2	SKE008-7	SKE052-1
SKE008-110	SKE054-3	SKE017-1	SKE008-8	SKE061-101	SKE007
SKE060-1	SKE060-2	SKE016-3	SKE016R	SKE582	SKE082
SKE165	SKE015-3	SKE054-101	SKE054-10	SKE803	SKE025
SKE009	SKE013-4	SKE013-5	SKE055-7	DTS02	SKE010-D
SKE057	SKE014	SKE710	SKE013-6	SKE013-7	SKE029
SKE708	SKZ006-1	SKE014-6	SKE001-5	SKE001-6	SKE005-1
SKE016-4	SKZ016-5	SKE010-2	SKE054-4	SKE054-7	SKE054-8
SKE054-6	SKE055-5	SKE055-4	SKE052-2	SKE063-2	SKE066-1
SKE053-4	SKE053-5	SKE013-2	SKE001-2	SKE002	SKE008-3
SKE054-1	SKE054-2	SKE055-3	SKE008-2	SKE010	SKE010-1
SKE011	SKE012	SKE013-1	SKE015-1	SKE016	SKE016-1
SKE016-2	SKE017	SKE018	SKE018-1	SKE019-1	SKE023
SKE024	SKE021	SKE022	SKE051	SKE053	SKE053-1
SKE054	SKE055	SKE056	SKE062-1	SKE063-1	SKE064
SKE065	SKE042	SKE001-1	SKE003	SKE004	SKE019
SKE044	SKE041	SKE043	SKE060	SKE061	SKE062
SKE071	SKE072	SKE073	SKE074	SKE075	SKE076
SKE077	SKE078	SKE079	SKE013(1)	SKE056-1	SKE014-1
SKE001-8	SKE001-9	SKE001-10	SKE001-12	SKE001-13	SKE001-14
SKE001c	SKE014-7	SKE014-8	SKE014-9	SKE001-16	SKE001-19
SKE-131	SKE-132	SKE-133	SKE-134	SKE-180A	SKE-188A

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SKE095	SKE135	SK1D-0A2Z	SK1D-0A1Z	SK1D-0B1	SL1D-0D2
SK1D-0E2	SK1D-0F2	SK1D-0F1	SK1D-2A1Z	SK1D-2C1	SK1D-2E2
SK1D-2F1	SK1D-3A0	SKE005-2	SKE089	SKE098	SKE-101
SKE-A1	SKE-B0	SKE-B1	SKE-B2	SKE-C0	SKE-C3
SKE-C4	SKE-D3	SKE008-4	SKE008-5	SKE008-6	SKE008-101
SKE008-102	SKE008-103	SKE008-G2	SKE008-G3	SKE011-1	SKE011-2
SKE027	SKE028	SKE034	SKE035	SKE039	SKE015-6
SKE015-7	SKE016-6	SKE017-5	SKE019-3	SKE020-1	SKE020-2
SKE020-3	SKE020-4	SKE020-10	SKE020-12	SKE020-1D	SKE020-2D
SKE020-3D	SKE020-4D	SKE049	SKE063-6	SKE099	SKE164
SKE170	SKE171	SKE171-1	SKE177	SKE178	SKE188
SKE407	SKE603	SKE606	SKE612	SKE689	SKE692
SKE693	SKE694	SKE695	SKE700	SKE703-1	SKE713
SKE714	SKE715	SKE716	SKE750	SKE805	SKE806
SKE807	SKE941	SKE942	SKE943	SKE017-8	SKE015-9
DM-Y106	SKE143	SKE180	SKJ-I	SKJ-II	SKE030
SKE030-8	SKE036	SKE040	SKE101	SKE102	SKE103
SK1E-103-2	SKE112	SKE112-1	SKE118	SKE130	SKE131
SKE145	SKE146	SKE147	SKE148	SKE149	SKE150
SKE151	SKE152	SKE153	SKE154	SKE155	SKE155(1)
SKE156	SKE157	SKE161	SKE162	SKE166	SKE167
SKE401	SKE412	SKE422	SKE696	SKE697	SKE698
SKE699	SKE709	SKE718	SKE719	SK1E-A1	SK1E-A2
SK1E-B1	SK1E-B2	SK1E-C1	SK1E-C2	SK1E-C3	SK1E-C4
SK1E-C5	SK1E-C6	SK1E-C7	SK1E-C8	SK1E-C9	SK1E-C10
SK1E-C11	SK1E-D1	SK1E-D2	SK1E-E1	SK1E-E2	SK1E-E3

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