



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
EMDN: V080202
Product Name: Medical Chair
Model/Size: See 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/A11: 2021	ISO 15223-1: 2021/Amd1: 2025
EN ISO 20417: 2021	EN ISO 10993-1: 2020
EN ISO 10993-5: 2009/A11: 2025	EN ISO 10993-10: 2023
EN ISO 10993-23: 2021/A1: 2025	

Signature: *Bessie WANG*

Date: *Jan 30, 2026*

江苏赛康医疗设备股份有限公司
Position: GM

Place: JIANGSU SAIKANG MEDICAL EQUIPMENT CO., LTD.
Jiangsu / China

Annex

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

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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	SKE095	SKE135	SK1D-0A2Z
SK1D-0A1Z	SK1D-0B1	SK1D-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	SKE020-20	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	SKE103-2
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

Bessie WANG

Jan 30, 2016

江苏康卫医疗设备股份有限公司
JI SU KANG WEI YI SHI BIAO GUAN
SAIKANG MEDICAL EQUIPMENT CO., LTD.

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	SKE168	SKE691
SKE104	SKE195			

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

Bessie WANG

Jan 30, 2028