



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
SRN: CN-MF-000002228
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: See Annex
Intended Use: Dialysis chairs are specialized medical furniture designed for patients undergoing hemodialysis, a medical procedure used to filter waste products and excess fluids from the blood when the kidneys are unable to perform this function effectively.
Basic UDI-DI: 697453996MedicalChairGE
Classification: Class I
Rule: Rule 1, Rule 13, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, we, the manufacturer herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following standards.

EN ISO 14971: 2019/A11: 2021	ISO 15223-1: 2021/Amd 1: 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	IEC 60601-1:2005+AMD1:2012+AMD2:2020
IEC60601-1-2:2014	

With reference to the electrical and electronic equipment listed in the Annex, it is also declared that such equipment are in conformity with the Directive 2011/65/EU and Directive (EU) 2017/2102 of the European Parliament and of the Council and Commission Delegated Directive (EU) 2015/863 on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment.

Signature: *Bessie Li* Position: General Manager

Date: *November 27, 2025* Place: Jiangsu / China

江苏赛康医疗设备股份有限公司
Jiangsu Saikang Medical Equipment Co., Ltd.

江苏赛康
Jiangsu Saikang

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	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	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
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	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

Bessie WPN9

November 27, 2025
江苏赛康医疗设备股份有限公司
Jiangsu Saikang Medical Equipment Co., Ltd.

限公司
Co., Ltd.