



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: Manual Hospital Bed
Model/Size: See Annex
Intended Use: Manual Hospital Beds is a bed specially designed for hospitalized patients or others in need of some form of healthcare

Basic UDI-DI: 697453996MHospitalBedVP

Classification: Class I
Rule: Rule 1, 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	

Signature: Bessie WAN

Position: GM

Date: November 21, 2025

Place: Jiangsu / China

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

Annex

A1K	A2K	A3K	B4w
D2w	D3d	D3w	V1k
V2k	V2w	V3k	V3v
V3w	V4w	V4v	Y2w
Y3w	CD3q	CR0q	CR2q
CT2k	CX2x	GT3K	X01-1
X01-5	X07a	X09	X14
X20	SK033-1	SK056-1	SK057-1
SK062-1	SK-A1	SK-AD1	SK-A2
SK-AD2	SK-A3	SK-AD3	SK-A4
SK-AD4	SK-B1	SK-BD1	SK-B2
SK-BD2	SK-B3	SK-BD3	SK-B4
SK-BD4	SK-C1	SK-CD1	SK-C2
SK-CD2	SK-C3	SK-CD3	SK-C4
SK-CD4	SK-C5	A4k	A2n
A2w	A3w	A4w	B0w
B1a	B2e	B3e	B4e
B2k	B3k	D2k	D3k
E1k	F1k	F2k	F4w
H2h	H2k	H3k	N1k
N2n	N2w	N3w	R1k
S0k	T2k	Y2k	Y3k
Y4y	Y1w	CR1q	CT1k
GA3k	GA4k	GB3e	GB4e
GB3k	GB4k	GN4k	X01(1)
X01-4	X01-6	X01-H	X02
X03-1M	X05-1	X05-2	X05-3
X05-5	X07	X11-1	X17
X42	A100s	A105s	E108s
R000s	R000w	R100s	R105s
R105w	S100s	S105s	SK042-5
SK057-3	SK062	SK062-3	SK063
SK066	SK067	SK068	SK069

Bessie WANG

November 21, 2025
 江苏赛康医疗设备股份有限公司
 Jiangsu Saikang Medical Equipment Co., Ltd.

疗设备股份有
 Medical Equipment

SK-TB008	SK-TB009	K2k	K3k
Q2w	CQ2k	SK-CHD01	X01
SK-PB018	SK-PB021	SK-PB023	SK-PB025
K4k	SK-AE1	SK-AF1	SK-AE2
SK-AF2	SK-AE3	SK-AF3	SK-AE4
SK-AF4	SK-BE1	SK-BF1	SK-BE2
SK-BF2	SK-BE3	SK-BF3	SK-BE4
SK-BF4	SK-CE1	SK-CF1	SK-CE2
SK-CF2	SK-CE3	SK-CF3	SK-CE4
SK-CF4	SKG-2A	SKG-3A	SKG-4A
SKZ-A	SKZ-AD	SKZ-B	SKZ-BD
SKZ-C	SKZ-CD	SK1A-A	SK1A-AD
SK1A-B	SK1A-BD	SKV-AC	SKV-AD
SKV-AE	SKV-BC	SKV-BD	SKV-BE
SKI-A	SKI-AD	SKI-B	SKI-BD
SKI-C	SKI-CD		

Passie WANG November 21, 2015
江苏赛康医疗设备股份有限公司
Jiangsu Saikang Medical Equipment Co., Ltd.

有限公司
Co., Ltd.