



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: Refer to Annex
Intended Purpose: 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	EN ISO 15223-1: 2021
EN ISO 20417:2021	EN ISO 10993-1: 2020
EN ISO 10993-5: 2009	EN ISO 10993-10: 2013
IEC 62366-1:2015/AMD1:2020	

Signature: Bessie WANG
Position: GM
Date: Aug 8th 2022
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
V2k5c	V2w	V3k5c	V3v
V3w	V4w	V4v	Y2w
Y3w	CD3q	CR0q	CR2q
CT2k	CX2x	GT3K	SK-C5
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			

份有限公司
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