



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: Electric Hospital Bed

Model/Size: Refer to Annex

Intended Purpose: The patient can perform daily basic care through the remote control, which is convenient for nursing.

Basic UDI-DI: 697453996EHospitalBedVP

Classification: Class I

Rule: 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	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 60601-2-52:2009/AMD1:2015	IEC 60601-1:2005+A1:2012+A2:2020
IEC 60601-1-2:2014+A1:2020	IEC 62366-1:2015/AMD1:2020

It is also declared that the above-mentioned products 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 WANG
Position: GM
Date: Aug 8th 2022
Place: Jiangsu / China

康医疗设备股份有限公司
KANG MEDICAL EQUIPMENT CO., LTD.

Annex

A6k	B6e	B8e	D6w
D8d	H6k	V6k5c	V6v
V6w	V8v8c	V8w	X9x
Y6t	Y6w	Y6y	Y8t
Y8y	X12	X26	X27
Z0n	GB8e	CT8k	HB300
HB400	HB421	HB422	HB423
HB424	HB425	HB426	HC200
HC300	HC400	HD421	HD422
SKD-A	SKD-B	SKD-C	

有限公司
NT CO., LTD