



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: See Annex

Intended Use The intended use of the Electric hospital bed is that the patient can perform daily basic care such as sitting, turning over, and urination through the remote control which is convenient for nursing and simple to operate. Generally used for ward.

Basic UDI-DI: 697453996EHospitalBedLF

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	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	BS EN 60601-2-52:2010+A1:2015
IEC 60601-1:2005+AMD1:2012+AMD2:2020	IEC60601-1-2:2014

It is also declared that the aboved-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: General Manager
Date: *March 17, 2026* Place: Jiangsu / China

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

江苏赛康医疗设备
Jiangsu Saikang Medical

Annex

A6k	B6e	B8e	D6w	D8d
H6k	V6k	V6v	V6w	V8v
V8w	X9x	Y6t	Y6w	Y6y
Y8t	Y8y	D7d	C8c	GB8e
CT8k	HB300	HB400	HB421	HB422
HB423	HB424	HB425	HB426	HC200
HC300	HC400	HD421	HD422	SKD-A
SKD-B	SKD-C			

Bessie WANG

March 17, 2026

股份有限公司
Equipment Co., Ltd.