



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 An examination table is integral to patient comfort while suffering from injury, trauma or shock.
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 WONG*

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.

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

Annex

X26	X23	X36	X12
X40	X15	Z0n	SKE005-10
SKF-A	SKF-B	SKF-B	SKZ-A
SKZ-AD	SKZ-B	SKZ-BD	SKZ-C
SKZ-CD	SKD-A	SK-BD1	SK-A1
X41	X42	X36-1	

Bessie WONG

November 27, 2025

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

有限公司
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