

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: Everbiz GmbH
Address: Landsberger Str.155 80687 München Germany
SRN: DE-AR-000008964

Product Name: Hospital Bed Accessories
Model/Size: Refer to Annex
Intended Use: Used for the components of a hospital bed to support
normal functions.

Basic UDI-DI: 697453996HBAccessories3P

Classification: Class I
Rule: Rule 1, 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	IEC 60601-1:2005+AMD1:2012+AMD2:2020
IEC60601-1-2:2014	

With reference to the electrical and electronic equipment listed in the Annex, it is also declared that such equipment 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
Jiangsu Saikang

Annex

Product Name	Product Model
Hand Controller	E3D, E3G, E3W, E5a
Nurse Controller	H1R
Foot Pedal	E1b
IV Pole	Pa4, Pa1, Pa2
IV Stand	SKH041(1), SKH041(1)-2, SKH041-3,
	SKH041-4, SKH041(13), SKH041(14),
	SKH041(15), SKH041(16), SKH041(17),
	SKH041(19), SKH041(20), SKH041(21),
	SKH041(22), SKH041(23), SKH041(24),
	SKH041(25), SKH041(26)
Weighing Box	E8L
Junction Box	F7z
Battery	E8G
Integrated Controller	E8k
Power Filter	E8F-P
Screw Rod	M1G
Shoe Rack	Pe2
Bed Platform	S1F, S4C, S4B, V21-1
Siderail	G5C, D17-1, G6D, T20, V21-3, Y19-2,
	Z22-2, G3A
Headboard & Footboard	102A, 103A, D17-2, K23-1, V21-2, Y19-1,
	Z22-1
Drainage Hook	F5e, H2c
Monkey Pole Socket	F2c
Balkan Frame	P3C
Foot-end Traction Frame	P3C-2
Monkey Pole	P3A, P3C-1
Hanging Ring	P3F
Brake Pedal	F4g
Bumper Wheel	H2c, D8d-P, P5H, P5H-1, X9x-P
Electronic Control System	E8m
Electronic Brake System	E8n

Bessie WONG

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Mattress Stopper	H2c, Pd1
Caster	C3A, C5B, C5E, C6E, C5D
Emergency Stop Switch	C4S
Oxygen Cylinder Holder	P4A
Underbed light	E5G
Saline Hook	H2c
Lifting Mechanism	C3K
Chasis	S3B
Adapter Cable	E5S
Motor	E5X, E8D, E6c
Damper	B2m, F3F, H2m
CPR	F4x
Power Cable	E8H
Signal Cable	C4m
Corner Protector	A900-P, K23-P
Chasis Cover	H2c
Socket	B2a
Controller	E8F
Battery Box	E8G
Sensor	E8J
Foot Switch	F8k
IV Pole Socket	Pa4-P
Headboard & Footboard Switch	Y19-P
Headboard & Footboard Socket	Y19-P
Wire Basket	W1A

Bessie C/STG

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