



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: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

SRN: NL-AR-000000247

Product Name: Electric operating table

Model/Size: Refer to Annex

Intended Purpose: The electric operating table is used for maternity, childbirth, and diagnosis, and for carrying patients during surgery

Basic UDI-DI: 697453996EOTableR9

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 60601-2-46:2016

IEC 60601-1-2:2014+A1:2020

IEC 60601-1:2005+A1:2012+A2:2020

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

江苏赛康医疗设备股份有限公司
JIANGSU SAIKANG MEDICAL EQUIPMENT CO., LTD.

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

Annex

A98-1S	A98-2	A98-3	A98-4
A98-9	A98NE	A99-1	A99-5
A99-6	A99-7	A99-8	A99-12
A99-13	A99-14	A99F	A100-4
A100-4A	A100-4B	A106-2	A106-3
A106-3A	A106-3S	A109-2	A110
A200	A200-1	A201	A202
A301	A302	A401	A501
A2000	A3000B	SKL-A	SKL-B
SKL-C	SKL-D	SKL-E	SKT-A
SKT-B	SKT-C		

公司
CO., LTD.