



# 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

**EC Representative:** SUNGO Europe B.V.  
**Address:** Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

**Product Name:** Electric operating table  
**Model/Size:** A100-4A, A100-4, A106-2, A99-1, A99-7, A98-3, A99-8

**SRN:** CN-MF-000002228      **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

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following harmonized standards.

EN ISO 14971: 2019	EN ISO 15223-1: 2016
EN 1041:2008+A1:2013	ISO 10993-1: 2018
EN ISO 10993-5: 2009	EN ISO 10993-10: 2013
IEC 60601-2-46:2016	IEC60601-1-2:2005+A1:2015
IEC 60601-1-1:2001+A1:2004	IEC 62366-1:2015

Signature: Bessie WANG

Position: GM

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

Date: June 4th, 2021

Place: Jiangsu / China