



# 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:** Operating Table  
**Model/Size:** A3008A-1, A048, A046, A045-1, A105

**SRN:** CN-MF-000002228      **Basic UDI-DI:** 697453996OperatingTable9Q

**Classification:** Class I  
**Rule:** Rule 1, 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 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