



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: Medical Trolley
Model/Size: See Annex

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

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.

*On behalf of SUNGO Europe office, I confirmed we are
 EU REP of the company who issue this document.*



Authorized Signature (S)

Date: June 4th, 2021

Place: Jiangsu / China

江苏赛康医疗
 JIANGSU SAIKANG MEDICAL EQUIPMENT CO., LTD.

Annex

SKR-AB00	SKR-A01	SKR-B00	SKR-IB00	SKR-J10
SKR-J21	SKR054-ET	SKR051-ET	SKR054-AT	SKR054-MT
SKR-CT750-1	SKR-ET625	SKR-AT625-1	SKR-MT625	SKR-CT625-1
SKR004	SKR007	SKR021-8	SKR022	SKR001-2
SKR002-3	SK-MT650	SK-ET750	SK-ET75077A	SK-AT75077A2
SK-CT75077C2	SKR-ET085	SKR-CT600	SKR-MT606	SKR-CT232
SKR-CT601	SKR-CT670	SKR-CT670-1	SKR-AT670	SKR-ET670
SKH040	SKH040-1	SKH027	SKR-WC561	SKH006C
SKH006	SKH001	SKH002	SKH006-1	SKH004
SKH006-5	SKH005	SKH029	SKH018	SKH032
SKH012	SKH021	SKH019	SKH028	SKH007-1
SKH013	SKH014	SKH105	SKH048	SKR024
SKR-MT670-2	SKR-MT670	SKR-MT670-1	SKR-CT670-2	SKR670
SKS009-2	SKS025			

设备股份有限公司
DICAL EQUIPMENT CO., LTD.

*On behalf of SUNGO Europe office, I confirmed we are
EU REP of the company who issue this document.*



Authorized Signature (S)



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

Date: June 4th, 2021

Place: Jiangsu / China

*On behalf of SUNGO Europe office, I confirmed we are
 EU REP of the company who issue this document.*



[Handwritten Signature]
 Authorized Signature (S)



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 |

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



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.

Authorized Signature (S)

Date: June 4th, 2021

Place: Jiangsu / China