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:	Manual Hospital Bed
Model/Size:	D3d, D3w, D2w, B4w, A3K, A2K, A1K, GT3K, CX2x, CR0q, CR2q, CD3q, CT2k, X01-1, X01-5, X20, X14, X07a, X09, SK033-1, SK056-1, SK057-1, SK062-1

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

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 22nd, 2021

Place: Jiangsu / China

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

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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 Hospital Bed
Model/Size:	Refer to Annex

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

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 60601-2-52:2009	IEC60601-1:2005+A1:2015
IEC 60601-1-2:2001+A1:2004	IEC 62366-1:2015

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

Signature: Bessie WANG

Position: GM

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

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Date: July 7th, 2021

Place: Jiangsu / China

Authorized Signature (S)

Annex

Y8y	Y6y	Y6w	X9x
D8d	D6w	B8e	B6e
A6k	H6k	GB8e	CT8k
Z0n	X12	X26	X27
Y8t	Y6t	HB400	HB300
HC200	HC300	HC400	

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

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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.

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

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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.

Sungo global service

Authorized Signature (S)

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

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:	Stretcher
Model/Size:	Refer to Annex

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

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.

Date: July 2nd, 2021

Place: Jiangsu / China

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Annex

SKB040(A001)	SKB040(A002)	SKB040(A004)	SKB040(A006)	SKB2A14
SKB2A10	SKB2A11	SKB2A12	SKB2A13	SKB-1A
SKB2C01	SKB1C10	SKB1C01-1	SKB1C02-1	SKB039(A)
SKB039(E)	SKB039(C)	SKB039(D)	SKB037(A)	SKB037(B)
SKB037(C)	SKB038-2	SKB038-4	SKB041-3S	SKB041-1
SKB041-2	SKB041-3	SKB041-6	SKB041	SKB039(E)-1
SKB039(B)	SKB039(C1)	SKB039(C2)	SKB039(C3)	SKB039(F)
SKB039(G)	SKB040(A)	SKB040(B)	SKB039(H)	SKB040(E)
SKB039-101	SKB039(K)	SKB1A01	SKB1A02	SKB1A01-1
SKB1A04	SKB1A05	SKB1A06	SKB1A07	SKB1A08
SKB1A09	SKB1A10	SKB1A11	SKB1A12	SKB1A 13
SKB1A14	SKB1B01	SKB1B02	SKB1B03	SKB1A15
SKB1A01-2	SKB1A02-1	SKB1A03	SKB1B01-1	SKB1B02-1
SKB1B04	SKB1C01	SKB1C02	SKB1C03	SKB1C04
SKB1C05-1	SKB1C06	SKB1C07	SKB1C08	SKB1C09
SKB1C05	SKB1C05-2	SKB1C09-1	SKB1C11	SKB1C02-2
SKB1C12	SKB2A07	SKB2A08	SKB2A09	SKB2A11-1
SKB2A01	SKB2A02	SKB2A03	SKB2A04	SKB2A05
SKB2A06	SKB2A09-1	SKB2A04-1	SKB2B07	SKB2B01
SKB2B02	SKB2B03	SKB2B04	SKB2B05	SKB2C02
SKB2C03	SKB2C04	SKB3A006	SKB3A002	SKB3A005
SKB3A001	SKB3A001(1)	SKB3A102	SKB3A101	SKB3A104
SKB3A103	SKB3C01	SKB3C02	SKB3C03	

有限公司 SUNGO CO.,LTD.

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

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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:	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.

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.

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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
ICAL EQUIPMENT CO., LTD.

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

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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:	Bedside Table
Model/Size:	Refer to Annex

SRN: CN-MF-000002228 **Basic UDI-DI:** 697453996BedsideTableH5

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

Signature: Bessie WANG

Position: GM

Date: July 2nd, 2021

Place: Jiangsu / China

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.

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Annex

SKS002	SKS002-W	SKS002-1	SKS002-2	SKS003
SKS005	SKS008	SKS007	SKS013-1	SKS009-2
SKS006-1	SKS020	SKS019	SKH046-11	SKH046-2
SKH046-14	SKH042	SKH046-1	SKS007-3	SKS009-6
SKS-19-1	SKS028	SKS029	SKS201-1	SKS055
SKS057	SKS005-2	SKS002-C	SKS013-C	SKS203
SKS204	SKS022	SKS009-5	SKS009-3	SKS009-4
SKS005-3	SKS016-1	SKS030	SKS023	SKS024
SKS010-2	SKS021	SKS019	SKS020	SKS205
SKS013-1	SKS206	SKS208	SKS003-1	SKS011-3
SKS005-101	SKS056	SKS011-101	SKS001-101	SKS003-101
SKR707	SKR709	SKS201	SKS207	SKS006-1
SKS02-W	SKS03-W	SKS02	SKS03	SKS001
SKS002-3	SKS004	SKS006	SKS009	SKS011
SKS007-2	SKS012-1	SKS013	SKS014	SKS015
SKS016	SKS017	SKS010	SKS010-S	SKS007-1 (01)
SKS005-1	SKS011-2	SKS018	SKS102	SKS101
SKS002-5	SKS103	SKS007	SKS009-1	

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

Sungo global service

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:	Medical Chair
Model/Size:	Refer to Annex

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

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

Signature: Bessie WANG

Position: GM

Date: July 2nd, 2021

Place: Jiangsu / China

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

Sungo global service

Authorized Signature (S)

Annex

SKE001	SKE001-3	SKE001-4	SKE014-5	SKE824	SKE-120B
SKE-120A	SKE-180	SKE-170A	SKE-100A	SKE087	SKE091
SKE090	SKE004-1	SKE005	SKE008-1	SKE008	SKE006-1
SKE006-2	SKE802	SKE015-2	SKE801	SKE015-5	SKE013
SKE015-4	SKE013-11	SKE013-10	SKE017-4	SKE702	SKE055-8
SKE031	SKE053-2	SKE052	SKE711	SKE712	SKE088
SKE054-9	SKE055-6	SKE054-5	SKE581	SKE568	SKE163
SKE014-2	SKE014-3	SKE019-2	SKE066	SKE048	SKE055-2
SKE704	SKE705	SKE706	SKE7010	SKE063	SKE001-7
SKE804	SKE001-4-P	SKE059	SKZ705	SKE701	SKE703
SKE013-3	SKE008-109	SKE069	SKE017-2	SKE008-7	SKE052-1
SKE008-110	SKE054-3	SKE017-1	SKE008-8	SKE061-101	SKE007
SKE060-1	SKE060-2	SKE016-3	SKE016R	SKE582	SKE082
SKE165	SKE015-3	SKE054-101	SKE054-10	SKE803	SKE025
SKE009	SKE013-4	SKE013-5	SKE055-7	DTS02	SKE010-D
SKE057	SKE014	SKE710	SKE013-6	SKE013-7	SKE029
SKE708	SKZ006-1	SKE014-6	SKE001-5	SKE001-6	SKE005-1
SKE016-4	SKZ016-5	SKE010-2	SKE054-4	SKE054-7	SKE054-8
SKE054-6	SKE055-5	SKE055-4	SKE052-2	SKE063-2	SKE066-1
SKE053-4	SKE053-5	SKE013-2	SKE001-2	SKE002	SKE008-3
SKE054-1	SKE054-2	SKE055-3	SKE008-2	SKE010	SKE010-1
SKE011	SKE012	SKE013-1	SKE015-1	SKE016	SKE016-1
SKE016-2	SKE017	SKE018	SKE018-1	SKE019-1	SKE023
SKE024	SKE021	SKE022	SKE051	SKE053	SKE053-1
SKE054	SKE055	SKE056	SKE062-1	SKE063-1	SKE064
SKE065	SKE042	SKE001-1	SKE003	SKE004	SKE019
SKE044	SKE041	SKE043	SKE060	SKE061	SKE062
SKE071	SKE072	SKE073	SKE074	SKE075	SKE076
SKE077	SKE078	SKE079	SKE013(1)	SKE056-1	SKE014-1

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

Sungo global service

Authorized Signature (S)