



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

Date: June 22nd, 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 confirm that we are EU REP of the company who issue this document.



[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 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

Signature: Bessie WANG *half of SUNGO Europe office, I confirmed we are*
EC REP of the company who issue this document.

Position: GM

Date: July 7th, 2021

Place: Jiangsu / China

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

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global service

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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.*



A handwritten signature in blue ink, appearing to read "J. Smith", written over a horizontal blue line.

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.

Sungo
EU REP

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



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

Date: *July 2nd, 2021*

Place: Jiangsu / China

江苏赛康医疗器械股份有限公司
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

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 公司
SKB1B04	SKB1C01	SKB1C02	SKB1C03	SKB1C04 公司
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	

On behalf of SUNGO Europe office, I confirmed we are
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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

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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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
DIGALEQUIPMENT 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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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.

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[Signature]
Authorized Signature (S)

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.*



[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: 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

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



[Signature]
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.



[Handwritten Signature]

Authorized Signature (S)



This is to certify that the Quality Management System of

Jiangsu Saikang Medical Equipment Co.,Ltd

Unified Social Credit Code: 91320582737846641U

Operation Address: No.35 Lehong Road, Modern Agriculture Demonstration Park, Zhangjiagang City, Jiangsu Province, China

Registered Address: No.35 Lehong Road, Modern Agriculture Demonstration Park, Zhangjiagang City, Jiangsu Province, China

applicable to

Design, produce and sale of electric hospital bed, electric cervical vertebra traction chair, multi-purpose manual and hydraulic operation table, traction bed, hospital bed, orthopedics traction bed, multi-purpose gynecological operation table, ambulance stretcher, scoop stretcher, stretcher, stair stretcher, foldable stretcher, patient trolley, stretcher trolley, medical trolley, electric operation table and examination table(within the scope of license)

has been assessed and registered by NQA against the provisions of

ISO 13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director

Certificate Number

34290

Date:

02 September 2010

Reissue Date:

29 July 2021

Valid Until:

30 August 2024



0015



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.



扫描全能王 创建

Certificate of Registration



This is to certify that the Quality Management System of

Jiangsu Saikang Medical Equipment Co.,Ltd

Unified Social Credit Code: 91320582737846641U

Operation Address: No.35 Lehong Road, Modern Agriculture Demonstration Park, Zhangjiagang City, Jiangsu Province, China

Registered Address: No.35 Lehong Road, Modern Agriculture Demonstration Park, Zhangjiagang City, Jiangsu Province, China

applicable to

Design, produce and sale of electric hospital bed, electric cervical vertebra traction chair, multi-purpose manual and hydraulic operation table, traction bed, hospital bed, orthopedics traction bed, multi-purpose gynecological operation table, ambulance stretcher, scoop stretcher, stretcher, stair stretcher, foldable stretcher, patient trolley, stretcher trolley, medical trolley, electric operation table and examination table(within the scope of license)

has been assessed and registered by NQA against the provisions of

ISO 9001:2015

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn)

SNQA's website: www.snqa.com.cn

Managing Director



0015



Certificate Number

29034

Date:

19 August 2013

Reissue Date:

29 July 2021

Valid Until:

30 July 2024

EAC Code:

23



The use of the UKAS Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 015 held by NQA.

NQA is a trading name of NQA Certification Limited, Registration No 09351758. Registered Office: Warwick House, Houghton Hall Park, Houghton Regis, Dunstable, LU5 5ZX, UK.

This certificate is the property of NQA and must be returned on request.



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中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号：苏苏药监械出 20202155 号

Certificate NO.: SSYJXC20202155

产品名称：见附件；

Product(s): See Attachment

规格型号：见附件；

Model: See Attachment;

产品注册或备案凭证号：见附件；

Registration certificate(s): See Attachment;

生产企业：江苏赛康医疗设备股份有限公司

Manufacturer: Jiangsu Saikang Medical Equipment Co.,Ltd.

生产企业住所：张家港市现代农业示范园区乐红路 35 号

Address of manufacturer: No.35 Lehong Road, Modern Agriculture Demonstration Park,
Zhangjiagang City, Jiangsu Province, China

生产许可或备案凭证号：苏苏食药监械生产备 20163002 号

Manufacturing License(s): NO.SSYJXSCB20163002

兹证明上述产品已准许在中国生产和销售。

**This is to certify that the above products have been registered to be
manufactured and sold in China.**

证明有效日期至：2022 年 11 月 20 日

This certification valid until: 2022-11-20

备注：/

Remark: /

江苏省药品监督管理局

2020 年 11 月 20 日



附件:

证书编号: 苏苏药监械出 20202155 号

Certificate NO.: SSYJXC20202155

序号 NO	产品名称 (中文) Product(s) (chinese)	产品名称 (英文) Product(s)	规格型号 (中文) Specification/model (c hinese)	规格型号 (英文) Specification/mode	产品注册证 或备案凭证 号(中文) Registration certificate(s)	产品注册证 或备案凭证 号(英文) Registration certificate(s)
1	铲式担架	Scoop Stretcher	SKX-B1 SKX-B2 SKX-B3 SKX-C1 SKX-C2	SKX-B1 SKX-B2 SKX-B3 SKX-C1 SKX-C2	苏苏械备 20160380 号	NO.SSXB201 60380
2	救护车担架	Ambulance Stretcher Trolley	SKC-2B1 SKC-2B2 SKC-2B3 SKC-1B1 SKC-1B2 SKC-3A9 SKC-3B4 SKC-3B5 SKC-3B6 SKC-3B7 SKC-3B10 SKC-3C4 SKC-3C5 SKC-3C9 SKC-3D4 SKC-3D5 SKC-3E4 SKC-3E5 SKC-3E8 SKC-3E9 SKC-3F5	SKC-2B1 SKC-2B2 SKC-2B3 SKC-1B1 SKC-1B2 SKC-3A9 SKC-3B4 SKC-3B5 SKC-3B6 SKC-3B7 SKC-3B10 SKC-3C4 SKC-3C5 SKC-3C9 SKC-3D4 SKC-3D5 SKC-3E4 SKC-3E5 SKC-3E8 SKC-3E9 SKC-3F5	苏苏械备 20160228 号	NO.SSXB201 60228
3	骨科牵引床	Orthopedics Traction Bed	SKG-2A SKG-3A SKG-4A SKG-2B SKG-3B SKG-4B SKG-2C	SKG-2A SKG-3A SKG-4A SKG-2B SKG-3B SKG-4B SKG-2C	苏苏械备 20160733 号	NO.SSXB201 60733



			SKG-3C SKG-4C	SKG-3C SKG-4C		
4	手动病床	Hospital Bed	SK-A1 SK-AD1 SK-A2 SK-AD2 SK-A3 SK-AD3 SK-A4 SK-AD4 SK-B1 SK-BD1 SK-B2 SK-BD2 SK-B3 SK-BD3 SK-B4 SK-BD4 SK-C1 SK-CD1 SK-C2 SK-CD2 SK-C3 SK-CD3 SK-C4 SK-CD4	SK-A1 SK-AD1 SK-A2 SK-AD2 SK-A3 SK-AD3 SK-A4 SK-AD4 SK-B1 SK-BD1 SK-B2 SK-BD2 SK-B3 SK-BD3 SK-B4 SK-BD4 SK-C1 SK-CD1 SK-C2 SK-CD2 SK-C3 SK-CD3 SK-C4 SK-CD4	苏苏械备 20160227 号	NO.SSXB201 60227
5	妇产科综合手术台	Surgical Table	SKF-A SKF-B SKF-C	SKF-A SKF-B SKF-C	苏苏械备 20160427 号	NO.SSXB201 60427
6	折叠担架	Folding Stretcher	SKA-1A SKA-2A SKA-3A SKA-4A SKA-1B SKA-2B SKA-3B SKA-4B SKA-1C SKA-2C SKA-3C SKA-4C	SKA-1A SKA-2A SKA-3A SKA-4A SKA-1B SKA-2B SKA-3B SKA-4B SKA-1C SKA-2C SKA-3C SKA-4C	苏苏械备 20160381 号	NO.SSXB201 60381



			SKA-1D SKA-2D SKA-3D SKA-4D SKA-1E SKA-1F SKA-2F SKA-3F SKA-4F SKA-1G	SKA-1D SKA-2D SKA-3D SKA-4D SKA-1E SKA-1F SKA-2F SKA-3F SKA-4F SKA-1G		
7	楼梯担架	Stair Stretcher	SKW-A1 SKW-B1 SKW-C1 SKW-A2 SKW-B2 SKW-C2	SKW-A1 SKW-B1 SKW-C1 SKW-A2 SKW-B2 SKW-C2	苏苏械备 20160379 号	NO.SSXB201 60379
8	转运车	Patient Transfer Trolley	SKK-A SKK-B	SKK-A SKK-B	苏苏械备 20160229 号	NO.SSXB201 60229
9	病人推车	Medical Trolley	SKM-A SKM-B SKM-C SKM-D SKM-E SKM-F SKM-G	SKM-A SKM-B SKM-C SKM-D SKM-E SKM-F SKM-G	苏苏械备 20160428 号	NO.SSXB201 60428
10	担架	Basket Stretcher	SKU-B1 SKU-C1 SKU-C2	SKU-B1 SKU-C1 SKU-C2	苏苏械备 20160460 号	NO.SSXB201 60460
11	担架	Stretcher	SKB-1A SKB-2A SKB-3A SKB-4A SKB-5A SKB-6A	SKB-1A SKB-2A SKB-3A SKB-4A SKB-5A SKB-6A	苏苏械备 20160426 号	NO.SSXB201 60426



中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL
PRODUCTS

证书编号：苏苏药监械出 20202298 号

Certificate NO.: SSYJXC20202298

产品名称：见附件；

Product(s): See Attachment

规格型号：见附件；

Model: See Attachment;

产品注册或备案凭证号：见附件；

Registration certificate(s): See Attachment;

生产企业：江苏赛康医疗设备股份有限公司

Manufacturer: Jiangsu Saikang Medical Equipment Co.,Ltd.

生产企业住所：张家港市现代农业示范园区乐红路 35 号

Address of manufacturer: No.35 Lehong Road, Modern Agriculture Demonstration Park,
Zhangjiagang City, Jiangsu Province, China

生产许可或备案凭证号：苏食药监械生产许 20030105 号

Manufacturing License(s): NO.SSYJXSCX20030105

兹证明上述产品已准许在中国生产和销售。

**This is to certify that the above products have been registered to be
manufactured and sold in China.**

证明有效日期至：2022 年 02 月 19 日

This certification valid until: 2022-02-19

备注：/

Remark: /

江苏省药品监督管理局

2020 年 12 月 07 日



附件:

证书编号: 苏苏药监械出 20202298 号

Certificate NO.: SSYJXC20202298

序号 NO	产品名称 (中文) Product(s) (chinese)	产品名称 (英文) Product(s)	规格型号 (中文) Specification/model (c hinese)	规格型号 (英文) Specification/mode	产品注册证 或备案凭证 号(中文) Registration certificate(s)	产品注册证 或备案凭证 号(英文) Registration certificate(s)
1	电动手术台	Electric Operating Table	SKL-A SKL-B SKL-C SKL-D SKL-E	SKL-A SKL-B SKL-C SKL-D SKL-E	苏械注准 20172540671	NO.SXZZ2017 2540671
2	治疗牵引床	Traction Bed	见附件 (苏械注准 20172260674)	See Attachment (NO.SXZZ20 172260674)	苏械注准 20172260674	NO.SXZZ2017 2260674
3	电动床	Electric Hospital Bed	SKD-A SKD-B SKD-C	SKD-A SKD-B SKD-C	苏械注准 20172560672	NO.SXZZ2017 2560672
4	液压综合手术 床	Hydraulic Multifunctional Operating Table	SKT-A SKT-B SKT-C	SKT-A SKT-B SKT-C	苏械注准 20172541476	NO.SXZZ2017 2541476
5	电动颈椎牵引 椅	Electric Traction Chair	见附件 (苏械注准 20172260673)	See Attachment (NO.SXZZ20 172260673)	苏械注准 20172260673	NO.SXZZ2017 2260673

附件（苏械注准20172260674）
Attachment（NO.SXZZ20172260674）

SKY- I
SKY- II
SKY- III
SKY-IV

附件（苏械注准20172260673）
Attachment（NO.SXZZ20172260673）

SKJ- I
SKJ- II



[Help \(./help/index.html\)](#)

[DRLM Home \(mainMenu.htm\)](#) ➤ [Change Registration Information for a Facility](#)

✓ Facility
✓ Products Listing

Update Registration Successful

Facility: JIANGSU SAIKANG MEDICAL EQUIPMENT CO., LTD , Zhangjiagang , Jiangsu, CHINA

Registration/FEI Number: 3010373263/3010373263

The Owner/Operator Number for this Registration is: 10043618.

Facility Information

Registration Number:
3010373263

Initial Importer:
N

Facility Name:
JIANGSU SAIKANG MEDICAL EQUIPMENT CO., LTD

Address:
NO.35 Lehong Road, Modern Agriculture Demonstration Park
Zhangjiagang, Jiangsu, 215600, CHINA

DUNS Number:

Foreign Trade Zone:
N

Facility URL:

Other Business Trade Name(s):

Owner/Operator Information

Owner/Operator Number:
10043618

Contact Name:
Zhixiang Cai

Company:
JIANGSU SAIKANG MEDICAL EQUIPMENT CO., LTD

Address: NO.35 Lehong Road , Modern Agriculture Demonstration Park
Zhangjiagang, JIANGSU, 215600, CHINA

Telephone:
086 - 512 - 58525850

Fax:
-

E-mail: bessie@zjgsaikang.com

DUNS Number:

Official Correspondent Information

Contact Name:

Zhixiang Cai

Company:

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Address:

NO.35 Lehong Road , Modern Agriculture Demonstration Park
Zhangjiagang, JIANGSU, 215600, CHINA

Telephone:

086 - 512 - 58525850

Fax:

-

E-mail:

bessie@zjgsaikang.com

DUNS Number:

United States Agent Information

Contact First Name

Hui

Contact Last Name

Hong

Contact Title:

Mr

Business Name:

ABMED SERVICE INC

Address:

1312 17th Street Suite 692
Denver, Colorado, 80202, UNITED STATES

Phone:

303 - 8000162

Fax:

DUNS Number:

E-mail:

info@abmed.com.cn

Device Listings					
Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities	Importers
D307226	Exempt	HSS	HALTER, HEAD, TRACTION	Contract Manufacturer Manufacturer	
D307225	Exempt	ITJ	WALKER, MECHANICAL	Manufacturer Contract Manufacturer	

D307228	Exempt	OVR	Kit, first aid, talking	Contract Manufacturer Manufacturer	
D307227	Exempt	NOC	Splint, extremity, non-inflatable, external, non-sterile	Manufacturer Contract Manufacturer	
D307224	Exempt	KNO	ACCESSORIES, WHEELCHAIR	Manufacturer Contract Manufacturer	
D307223	Exempt	ILS	ADAPTOR, HYGIENE	Manufacturer Contract Manufacturer	
D307229	Exempt	GAG	Stapler, surgical	Manufacturer Contract Manufacturer	
D307231	Exempt	CAN	REGULATOR, PRESSURE, GAS CYLINDER	Manufacturer Contract Manufacturer	
D307230	Exempt	EBR	UNIT, SUCTION OPERATORY	Contract Manufacturer Manufacturer	
D307237	Exempt	FLH	WASHER OF BODY WASTE RECEPTACLES	Contract Manufacturer Manufacturer	
D307236	Exempt	FMR	DEVICE, TRANSFER, PATIENT, MANUAL	Manufacturer Contract Manufacturer	
D307239	Exempt	FNM	MATTRESS, AIR FLOTATION, ALTERNATING PRESSURE	Manufacturer Contract Manufacturer	
D307238	Exempt	FMW	COVER, MATTRESS (MEDICAL PURPOSES)	Manufacturer Contract Manufacturer	
D187098	Exempt	BRY	CABINET, TABLE AND TRAY, ANESTHESIA	Manufacturer Foreign Exporter	MEDevice Services, LLC
D307233	Exempt	GDC	TABLE, OPERATING-ROOM, ELECTRICAL	Manufacturer Contract Manufacturer	
D307232	Exempt	FQP	Lamp, operating-room	Manufacturer Contract Manufacturer	

D307235	Exempt	BZN	CART, EMERGENCY, CARDIOPULMONARY (EXCLUDING EQUIPMENT)	Contract Manufacturer Manufacturer	
D187094	Exempt	FPP	STRETCHER, HAND-CARRIED	Manufacturer Foreign Exporter	MEDevice Services, LLC
D187095	Enforcement Discretion	FWZ	Operating Room Accessories Table Tray	Foreign Exporter Manufacturer	MEDevice Services, LLC
D187096	Exempt	KMN	CHAIR AND TABLE, MEDICAL	Manufacturer Foreign Exporter	MEDevice Services, LLC
D187097	Exempt	BWN	TABLE AND ATTACHMENTS, OPERATING-ROOM	Foreign Exporter Manufacturer	MEDevice Services, LLC
D187092	Exempt	FNL	BED, AC-POWERED ADJUSTABLE HOSPITAL	Manufacturer Foreign Exporter	MEDevice Services, LLC
D187093	Exempt	FNJ	BED, MANUAL	Manufacturer Foreign Exporter	MEDevice Services, LLC
D426004	Exempt	FIA	CHAIR, DIALYSIS, UNPOWERED, WITHOUT SCALES	Manufacturer	
D426005	Exempt	INQ	TABLE, POWERED	Manufacturer	
D426008	Exempt	HOK	Screen, tangent, projection, ac-powered	Manufacturer	
D426007	Exempt	FOX	STAND, INFUSION	Manufacturer	
D426011	Exempt	FQO	TABLE, OPERATING-ROOM, AC-POWERED	Manufacturer	
D388558	Exempt	FPO	STRETCHER, WHEELED	Manufacturer	

Date of Initial Registration: 2013-03-06 02:26:27.0