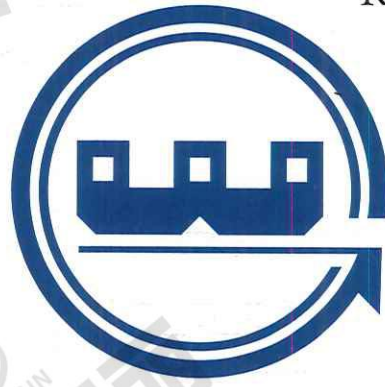


Registration No.: 00925Q10537R0S



**CHINA GREAT WALL (TIANJIN)
QUALITY ASSURANCE CENTRE CO., LTD.
QUALITY MANAGEMENT SYSTEM CERTIFICATE**

We hereby certify that

Tianjin Kangli Medical Appliance CO. Ltd

(Unified social credit code:91120222103927765D)

Registered address is located at: No. 5, Sheng yuan Road,
Fu yuan Economic Zone, Mei Chang Town, Wu Qing District, Tianjin.

Its quality management system meets the requirements of the
GB/T19001-2016/ISO9001:2015 Standard.

The quality management system applies in the following areas:

The production and service of electric bed, hand-crank bed, flat bed, ordinary delivery bed, patient trolley, medical car, medical cabinet, medical diagnosis and treatment bed, orthopedic traction bed. Sales and service of manual wheelchairs.

Date of Issuance: Apr. 15th, 2025

Date of Expiry: Apr. 14th, 2028

CHINA GREAT WALL (TIANJIN) QUALITY ASSURANCE CENTRE CO., LTD.

General Manager



中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C009-M

The certificate information (including certificate validity, supervision and maintenance of registration qualification and other information) can be scanned by the QR code of the certificate, and the website of the center can be used to check the information of the certificate (www.isocgw.net), and the official website of CNCA (www.cnca.gov.cn) Query on.

CGW Add: No. 4, Jinlong apartment, Water North road, Nankai District, Tianjin; Postal code: 300074;

The web of centre: www.isocgw.net

Registration No.: 00924E10223R4S



**CHINA GREAT WALL (TIANJIN)
QUALITY ASSURANCE CENTRE CO., LTD.
ENVIRONMENT MANAGEMENT
SYSTEM CERTIFICATION**

We hereby certify that
Tianjin Kangli Medical Appliance CO. Ltd

(Unified social credit code: 91120222103927765D)

Registered address is located at: Fuyuan Economic & Technological
Development Zone Meichang Town, Wuqing District, Tianjin, China.

Its environment management system meets the requirements of the
GB/T24001-2016/ISO14001:2015 Standard.

The environment management system applies in the following areas:

**2 type 6852 Hospital nursing equipments and appliance (KLD type electric bed)'s
production, 1 type medical instruments (medical cabinet, Medical clinic bed,
shaking bed, anesthesia table, plain medicative cart, portable obstetric table,
orthopedics bed, medical stretcher, manual wheelchair)'s production.**

Date of Issuance: Mar. 6th, 2024

Date of Expiry: Mar. 5th, 2027

CHINA GREAT WALL (TIANJIN) QUALITY ASSURANCE CENTRE CO., LTD.

General Manager



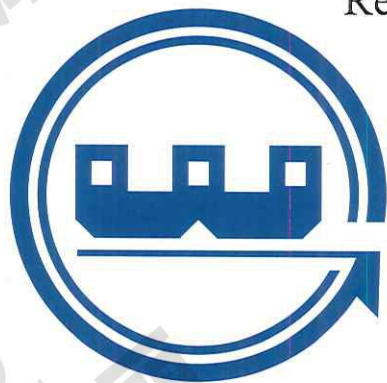
中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C009-M

The certificate information (including certificate validity, supervision and maintenance of registration qualification and other information) can be scanned by the QR code of the certificate, and the website of the center can be used to check the information of the certificate (www.isocgw.net), and the official website of CNCA (www.cnca.gov.cn) Query on.

CGW Add: No. 4, Jinlong apartment, Water North road, Nankai District, Tianjin; Postal code: 300074;

The web of centre: www.isocgw.net

Registration No.: 00924S10199R2S



**CHINA GREAT WALL (TIANJIN)
QUALITY ASSURANCE CENTRE CO., LTD.
OCCUPATIONAL HEALTH AND SAFETY
MANAGEMENT SYSTEM CERTIFICATE**

We hereby certify that
Tianjin Kangli Medical Appliance CO. Ltd

(Unified social credit code: 91120222103927765D)

Registered address is located at: **Fuyuan Economic&Technological
Development Zone Meichang Town, Wuqing District, Tianjin, China.**

Its occupational health and safety management system meets the requirements of the
GB/T45001-2020/ISO 45001:2018 Standard.

The occupational health and safety management system applies in the following areas:
**2 type 6852 Hospital nursing equipments and appliance (KLD type electric bed)'s
production, 1 type medical instruments (medical cabinet, Medical clinic bed,
shaking bed, anesthesia table, plain medicative cart, portable obstetric table,
orthopedics bed, medical stretcher, manual wheelchair)'s production.**

Date of Issuance: Mar. 6th, 2024

Date of Expiry: Mar. 5th, 2027

CHINA GREAT WALL (TIANJIN) QUALITY ASSURANCE CENTRE CO., LTD.

General Manager



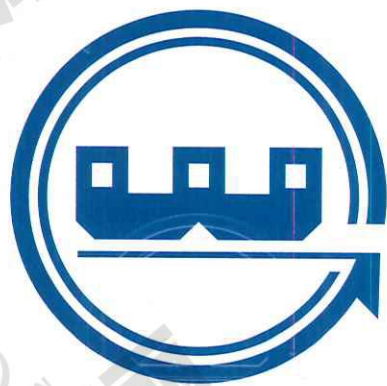
中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C009-M

The certificate information (including certificate validity, supervision and maintenance of registration qualification and other information) can be scanned by the QR code of the certificate, and the website of the center can be used to check the information of the certificate (www.isocgw.net), and the official website of CNCA (www.cnca.gov.cn) Query on.

CGW Add: No. 4, Jinlong apartment, Water North road, Nankai District, Tianjin; Postal code: 300074;

The web of centre: www.isocgw.net

Registration No.: Y25CC004



**CHINA GREAT WALL (TIANJIN)
QUALITY ASSURANCE CENTRE CO., LTD.
MEDICAL DEVICES QUALITY MANAGEMENT
SYSTEM CERTIFICATE**

We hereby certify that

Tianjin Kangli Medical Appliance CO. Ltd

(Unified social credit code:91120222103927765D)

Registered address is located at: No. 5, Sheng yuan Road,

Fu yuan Economic Zone, Mei Chang Town, Wu Qing District, Tianjin.

Its Medical devices Quality Management System meets the requirements of the
GB/T42061-2022/ISO13485:2016 Standard.

The Medical devices Quality Management System applies in the following areas:

The production and service of electric bed, hand-crank bed, flat bed, ordinary delivery bed, patient trolley, medical car, medical cabinet, medical diagnosis and treatment bed, orthopedic traction bed. Sales and service of manual wheelchairs.

Date of Issuance: Apr. 15th, 2025

Date of Expiry: Apr. 14th, 2028

CHINA GREAT WALL (TIANJIN) QUALITY ASSURANCE CENTRE CO., LTD.

General Manager



The certificate information (including certificate validity, supervision and maintenance of registration qualification and other information) can be scanned by the QR code of the certificate, and the website of the center can be used to check the information of the certificate (www.isocgw.net), and the official website of CNCA (www.cnca.gov.cn) Query on.

CGW Add:No. 4,Jinlong apartment,Water North road,Nankai District,Tianjin; Postal code:300074;

The web of centre:www.isocgw.net



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 12183:2014
ISO 13485:2016

Remark

The declaration of conformity is valid in connection
with the release technical document CE/MDR-
Y122103-04.

All the supporting documentation is retained at the
premises of the manufacturer.

The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.

Manufacturer

Name: TIANJIN KANGLI MEDICAL APPLIANCE
CO.,LTD

Address: NO.5, SHENGYUAN ROAD, FUYUAN
ECONOMIC REGION, MEICHANG TOWN,
WUQING DISTRICT, TIANJIN CHINA

SRN:

Product Information

Name: MANUAL WHEELCHAIR

Model: F-W01 F-W02 F-W03 F-W04 F-W05 F-W06
F-W07 F-W08 F-W09 F-W10 F-W11 F-W12 F-W13
F-W14 F-W15 F-W16 F-W17 F-W18 F-W19 F-W20
F-W21 F-W22 F-W23 F-W024 F-W25 F-W26 F-W27

GMDN: 37687

EMDN: Y122103

Basic UDI-DI: /

Classification: Class I, according to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

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

Signature: 

Date: 18th April, 2023

Position: GM

Place: Tianjin/China





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013

Remark

The declaration of conformity is valid in connection
with the release technical document
CE/MDR-V080602-02.

All the supporting documentation is retained at the
premises of the manufacturer.

The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.

Manufacturer

Name: TIANJIN KANGLI MEDICAL APPLIANCE
CO.,LTD
Address:NO.5, SHENGYUAN ROAD,FUYUAN
ECONOMIC REGION,MEICHANG TOWN,
WUQING DISTRICT,TIANJIN CHINA
SRN:

Product Information

Name: MANUAL HOSPITAL BED
Model: A-17 A-18 A-19 A-20 A-21 A-22 A-23 A-24
A-25 A-26 A-27 A-28 A-29 A-30 A-31 A-32 A-33 A-34
A-35 A-36 A-37 A-38 A-39 A-40 A-41 A-42 A-43 A-44
A-45 A-46 A-47 A-48 A-49 A-50 A-51 A-52 A-53 A-54
A-55 A-56 A-57 A-58 A-59 A-60 A-61 A-62 A-63 A-64
A-66 A-67 A-68 A-69

EMDN: V080602

GMDN: 34873

Basic UDI-DI: /

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

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

Signature: 

Date: 18th April, 2023

Position: GM

Place: Tianjin/China





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.

Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands

SRN: NL-AR-000000247

Manufacturer

Name: TIANJIN KANGLI MEDICAL APPLIANCE
CO.,LTD

Address: NO.5, SHENGYUAN ROAD,FUYUAN
ECONOMIC REGION,MEICHANG TOWN,
WUQING DISTRICT,TIANJIN CHINA

SRN:

Product Information

Name: MEDICAL TROLLEY

Model: B-1 B-2 B-3 B-4 B-5 B-6 B-7 B-8 B-9 B-10
B-11 B-22 B-23 B-24 B-25 B-26 B-27 B-28 B-29 B-30
B-31 B-32 B-33 B-34 B-35 B-36 B-37 B-38 B-39 B-40
B-41 B-42 B-43 B-44 B-45 B-46 B-47 B-48 B-49 B-50
B-51 B-52 B-53 B-54 B-55 B-56 B-57 B-58 B-59 B-60
B-61 B-62 B-63 B-64 B-65 B-66 B-67 B-68 B-69 B-70
B-71 B-72 B-73 B-74 B-75 B-76 B-77 B-78 B-79 B-80
B-81 B-82 B-83 B-84 B-85 B-86 B-87 B-88 B-89 B-90
B-91 B-92 B-93 B-94 B-95 B-96 B-97 B-98 B-99
B-100 B-101 B-102 B-103 B-104 B-105 B-106 B-107
B-108 B-109 B-110 B-111 B-112 B-113 B-114 B-115
B-116 B-117 B-118 B-119 B-120 B-121

EMDN: V9099

Basic UDI-DI: /

Classification: Class I, According to Rule 1, Annex
VIII, Regulation (EU) 2017/745

Declaration

Conformity Assessment

Conformity Assessment Procedure

Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019

EN ISO 15223-1: 2021

EN ISO 20417: 2021

EN ISO 10993-1: 2020

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013





DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971: 2019
EN ISO 15223-1: 2021
EN ISO 20417: 2021
EN ISO 10993-1: 2020
EN ISO 10993-5: 2009
EN ISO 10993-10: 2013
EN 60601-2-52: 2010/A1: 2015
EN 60601-1: 2006/ A2: 2020
EN 60601-1-2: 2015/A1: 2020

Remark

The declaration of conformity is valid in connection
with the release technical document
CE/MDR-V080601-01.

All the supporting documentation is retained at the
premises of the manufacturer.

The Declaration of Conformity is exclusively under
the sole responsibility of the manufacturer.

Manufacturer

Name: Tianjin Kangli Medical Appliance Co., Ltd
Address: No.5, Shengyuan Road, Fuyuan Economic
Region, Meichang Town, Wuqing District, Tianjin
China
SRN:

Product Information

Name: Electric Hospital Bed
Model: V-01 V-02 V-03 V-04 V-05 V-06 V-07 V-08 V-09
A-1 A-2 A-3 A-4 A-5 A-6 A-7 A-8 A-9 A-10 A-11 A-12
A-13 A-14 A-15 A-16
EMDN: V080601
GMDN: 34870
Basic UDI-DI: /
Classification: Class I, According to Rule 13, Annex
VIII, Regulation (EU) 2017/745

Declaration

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

Signature:  Date: 18th April, 2023

Position: GM

Place: Tianjin/China

