Certificate of Compliance

Certificate No.	:	**CTICAD206242621092488AC**
Applicant	:	Chengdu Haohan Medical Equipment Co., Ltd. No.7 Wangjiayan Street, Huangjia Street, Shuangliu District, Chengdu City, Sichuan
Manufacturer	:	Chengdu Haohan Medical Equipment Co., Ltd. No.7 Wangjiayan Street, Huangjia Street, Shuangliu District, Chengdu City, Sichuan
Product Name	:	hospital bed
Trade Name	:	HaoHan
Main Test Model	:	HH/SJC-II-G-010
Additional Model	:	HH/SJC-I-G-008 HH/SJC-II-G-009 HH/BC-F-3-G-022 HH/BC-F-2-G-037 HH/BC-F-3-G-038 HH/BC-F-2-G-039 HH/BC-F-3-G-040 HH/BC-L-ET-T-057 HH/QJC-195
Test Standard	:	**EN 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR.2(2007) + AM1 (2012) or EN 60601-1 (2012 reprint)**
As shown in the Test Report No.	:	**CTICAD206242621092488AR**

The EUT described above has been tested by us with the listed standards and found in compliance with the council LVD directive 2014/35/EU. It is possible to use CE marking to demonstrate the compliance with this LVD Directive.
The certificate applies to the tested sample above mentioned only and shall not imply an assessment of the whole production.

CTIC Testing Group (Guangdong) Co.,Ltd.
APPROVED
Manager
Sep.24,2024

CTIC Testing Group (Guangdong) Co., Ltd.
Add: 201, Building A1 Lilang International Jewelry industrial Park, No.31, BulanRoad,Xialilang Community,Nanwan Street, Longgang District,Shenzhen,Guangdong,China
Certificate Search: 400-6800-890 http://www.ctic-lab.com Email:Christina@ctic-lab.com

HUMISS

Certification of EU Medical Device Notification

This is to certify that, according Regulation (EU) 2017/745 of the European Parliament and of the Council,

Humiss International B.V.
Address: Joop Geesinkweg 701, 1114AB Amsterdam-Duivendrecht, the Netherlands

has fulfilled all notification responsibility and duty as the European Authorized representative of:

Manufacturer: Jiangsu Yongfa Medical Equipment Technology Co., Ltd.
Address: Changfeng Villiage, Leyu Town, Zhangjiagang City, Jiangsu Province,215622,China

The manufacturer has provided with all the appropriate declaration according the Regulation (EU) 2017/745 requirements including the EC Declaration of Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of Regulation (EU) 2017/745.

Product(s): Manual Operating Table
CIBG number: Yongfa (NL-CA002-2021-59522) ,CIBG-20213168
Model(s): YFST-Y05, YFST-Y06, YFST-J06
Classification: Class I

Where then manufacturer affixes the CE marking to the product listed, they must ensure that all the requirements of the appropriate EU regulation(s) have and continue to be met.

The notification of aforementioned device(s) has been completed by European Authorized representative in Netherlands, the Netherlands Competent Authority notified of the manufacturer's medical device and has allocated registration.

CE

This is only a CE mark sample which is only use for reference.

HUMISS INTERNATIONAL B.V.

Signature of Executive Director
James St. WU

Contact HUMISS
E-mail: ce-tech@humiss.com
Website: www.humiss.com

Cert. Nº: H-YQ-MD-210510019/03
Issue date:May. 10, 2021

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 10993-10:2023
EN ISO 10993-23:2021
EN 60601-1:2006/A2:2021
EN 60601-1-2:2015+A1:2021

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V0805030102-01.

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: Hebei Senmao Medical Equipment Co., Ltd

Address: 1-4, North District, No. 999 Kaiyuan Road, Jizhou District, Hengshui City, Hebei Province China

SRN: CN-MF-000047210

Product Information

Name: Lift and Shift Machine

Model: See Annex

EMDN: V0805030102

Basic UDI-DI: 697349061LiftandShiftMP5

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:2025.03.25

Position: GM Place: Hebei /China

Annex
Model
D-TC01;D-TC02;D-TC03;D-TX01;D-TX02;D-TX03;D-TL01;DTL02;D-TL03;D-BC01;D-BC02;D-BC03;D-BX01;D-BX02;D-BX03;D-BL01;D-BL02;D-BL03;D-LC01;D-LC02;D-LC03;D-LX01;D-LX02;D-LX03;D-LL01;D-LL02;D-LL03;D-TY01;D-TY02;D-BY01;D-BY02;D-LY01;D-LY02;Z-TD01;Z-TD02;Z-TD03;Z-TDY01;Z-TDY02;Z-LD01;Z-LD02;Z-LD03;Z-LDY01;Z-LDY02;Z-BD01;Z-BD02;Z-BD03;Z-BDY01;Z-BDY02;Z-TY01;Z-TY02;Z-TY03;Z-TY04;Z-TYY01;Z-TYY02;Z-BY01;Z-BY02;Z-BY03;Z-BY04;Z-BYY01;Z-BYY02;Z-LY01;Z-LY02;Z-LY03;Z-LY04;Z-LYY01;Z-LYY02;S-SY01;S-SY02;S-SY03;T-TG01;T-TG02;T-TG03;T-BG01;T-BG02;T-BG03;T-LG01;T-LG02;T-LG03;G-TC01;G-TC02;G-TC03;G-TX01;G-TX02;G-TX03;G-TL01;G-TL02;G-TL03;G-BC01;G-BC02;G-BC03;G-BX01;G-BX02;G-BX03;G-BL01;G-BL02;G-BL03;G-LC01;G-LC02;G-LC03;G-LX01;G-LX02;G-LX03;G-LL01;G-LL02;G-LL03

DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122103-01.

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: Hebei Xiangrun Medical Equipment Co., Ltd
Address: Bei Zhanghuai Downtown, JiZhou District, HengShui City, HeBei Province.
SRN:

Product Information

Name: Manual Wheelchair
Model: SYIV90-XR01
SYIV90-XR02
SYIV90-XR03
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: 2022.9.20

Position: GM

Place: Hebei/China

verification проверка verificación verification проверка verificación verification

VERIFICATION OF CONFORMITY

S/N: 013721

No.: **ICR/VC/HS250437/A1**

replaces **ICR/VC/HS250437**

Name and address of Applicant
XIAMEN LIYUAN METAL. CO.,LTD.
No.110-2 Qiatoushe Shanbiancun Dongfu Haicang, Xiamen, Fujian, 361027, CHINA

Name and address of manufacturer:
XIAMEN LIYUAN METAL. CO.,LTD.
No.110-2 Qiatoushe Shanbiancun Dongfu Haicang, Xiamen, Fujian, 361027, CHINA

Product name: Shower chair

Product types: L-3100KD-4; L-3100KD-4S; L-3100KD-5; L-3100KD-5S; L-3101KD-4; L-3102-4; L-3102-5; L-3102-5S; L-3105-4; L-3105-5; L-3105-5S; L-3106-4; L-3107-4; L-3109-4; L-3201-4; L-3201-5; L-3202-4; L-3301KD-1; L-3500X-4; L-3500X-4S; L-3501KD-1S; L-3503KD-4; L-3504KD-4; L-3504KD-4S; L-3504KD-5; L-3504KD-5S; L-3505KD-4; L-3506KD-4; L-3507KD-1; L-3507KD-2; L-3507KD-3; L-3508KD-1; L-3508KD; L-3510KD; L-3600KD-1; L-3601KD-1; L-3602KD-1; L-3603KD-1; L-3604KD-1; L-3605KD-1

Product trademark: n/a

Verification was carried within following scope:

Information on the Declaration of Conformity:

Result:	**Legislation:**	**Standard:**
✓	MDR [(EU) 2017/745]	EN ISO 14971:2019+A11:2021
		EN ISO 15223-1:2021
		EN ISO 20417:2021
		EN ISO 10993-1:2020
		EN ISO 10993-5:2009
		EN ISO 10993-10:2023
		EN ISO 10993-23:2021

The assessment process has been carried out in accordance with individual rules and conditions agreed with the applicant.
Evaluation has been carried out in accordance with:

Test report: TFMTCF0409-MDR
Tests conducted by: XIAMEN LIYUAN METAL. CO.,LTD.

Issue date: 09.04.2025
Expiration date: 08.04.2030

Remarks:
- VoC was issued on voluntary basis and does not imply meeting all essential requirements listed in Declaration of Conformity.
- For introducing this product on European market may be needed EC/EU-type examination conducted by appropriate Notified Body.

ICR Co. Ltd.
www.icrqa.com
www.icrpolska.com
cert@icrqa.com

CEO, ICR Co., Ltd.

CERTIFICATE | CERTIFICADO | ZERTIFIKAT | CERTIFICATO | 证书 | 証明書 | 인증서입니다 | شهادة

CERTIFICATE

Certificate No: BGTC20230711-02

Applicant:	Foshan Sunshine Healthcare Co., Ltd.
Name, address:	Room 1507-1, Building 3, Tian 'an Center, No. 31, Jihuadong Road, Guicheng Street,Foshan Province,Guangdong,China
Manufacturer:	Foshan Sunshine Healthcare Co., Ltd.
Name, address:	Room 1507-1, Building 3, Tian 'an Center, No. 31, Jihuadong Road, Guicheng Street,Foshan Province,Guangdong,China
Product:	Cane,Crutch,Walker,Rollator,Shower Chair,Commode Chair,Bath Bench, Bath Board,Toilet Seat Rasier,Urinal,Grab Bar,Hospital Bed,Overbed Table, Recliner Lift Chiar,Wheelchair,Ramp,Daily Living Aid,Wheels
Trademark:	
Type / Models:	GE-001
Related Directives and Annex:	Regulation (EU) 2017/745 (MDR)
Related Standards:	
Technical file:	TCF(23)-0704-MDR
Comments:	

This certificate is provided to the applicant on the basis of the information provided by the manufacturer or the applicant, and it gives to the applicant the right to use and affix the ECTI CERT Mark on their products accordingly to the ECTI CERT regulation for voluntary certification about its release and its use. The latest revision of the Regulation is available and can be downloaded from the website www.ecti-bg.com. Therefore, it does not imply any assessment on the safety and compliance of the product, or the production process of this product by ECTI CERT.

CE marking is only used on the product if all the relative EU Directives or Regulations are complied with. EC Declaration of Conformity and the technical documents are prepared by the manufacturer or its applicant who puts the product on the market.

11/Jul./2023 — Manager

Date of Issue

The validity of this certificate (5 years from the date of issue) can be checked on the ECTI CERT Homepage.

ECTI CERT Ltd.
Office 729, 133 Tsarigradsko Shosse Blvd., Sofia, Bulgaria
www.ecti-bg.com

Tel.: +359 878 87 75 77
E-mail: info@ecti-bg.com