

CERTIFICATE

Certificat - Certificado- Сертификат - Zertifikat - 證書

- 1) **APPLICANT:** (who finally puts the product on the market)
HI-LIFE TECHNOLOGY (HEBEI) CO.,LTD
67.2 KM OF THE SOUTH OF NO.112 HIGHWAY, BAZHOU, HEBEI PROVINCE, CHINA
- 2) **CERTIFICATE NO.:** I/SETC.002320190930
FILE REFERENCE: CE/MDD-LF-2019
- 3) **ISET MARK:**



- 4) **CAUTION ABOUT CE MARKING** (Instruction for the Applicant who puts the product on the EU market):



The label of the CE Marking on the left side should be not less than 5mm height. CE Marking and EC Declaration of Conformity are duties for the manufacturer or its applicant who puts the product on the market. This one is responsible to start the CE marking and certification procedure as required by the legislation in force. Only for the products which are compulsorily included into specific Directives or Regulations will be necessary to appoint a Notified Body.

- 5) **TYPE OF PRODUCT:** Manual Hospital Bed,Hospital Bed,Pediatric Hospital Bed,Infant Bed, Electric Delivery Bed
Gynecological Examination Couch,Examination Couch,Delivery Bed,Hospital Trolley,
Operating Table,Surgical Positioning Pad,Surgical Lithotomy stirrup Leg Holders,
Lateral Position Fixing System,Surgical Head Support ,Medical trolley,Medical cabinet,
Medical table,Patent Return Electrode Pad,Electric Hospital Bed,Electric Operating Table

MODEL(S): See the following annex I&II

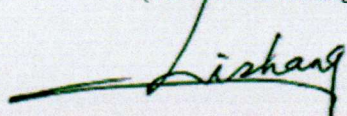
- 6) **LIST OF DIRECTIVES / REGULATIONS /STANDARDS** (as declared by the manufacturer itself)
Medical Device Directive 93/42/EEC, EN ISO 14971:2012, EN ISO 15223-1:2016,
EN 1041:2008, EN60601-1:2006/A1: 2013,EN60601-1-2:2015, EN 60601-2-52:2010
- 7) **NOTE:** The applicant is aware about the contents and information included in the ModCOM04.06 Regulation for this type of Certificate that is considered totally accepted. The latest revision of the Regulation is available and can be downloaded from the website www.iset-italia.eu. This document is not referred to any evaluation that could be considered as included in the scope of the activities covered by the standard BS EN ISO/IEC 17065:2012 or European Regulation 765/2008.
- 8) **REMARK:** Certificate is issued on voluntary application from the Client and it gives to the applicant the right to use and affix the ISET Mark (at point 3) on their products, even if it doesn't imply any assessment on the safety and compliance of the product. ISET declares that the only scope of the assessment is to verify the existence of the declaration issued by the manufacturer or an applicant under its own responsibilities.

- 9) **DATE OF ISSUE:** 30/09/2019

EXPIRY DATE: 29/09/2024

- 10) **SIGNATURE:** Li Zhang

(On behalf of the Legal representative)

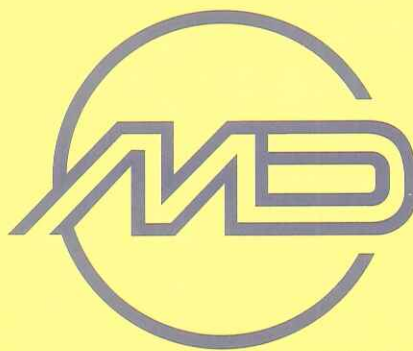



ANNEX I

Product Name	Type/ Size
Manual Hospital Bed	HL-A131A,HL-A131B,HL-A131C,HL-A132A,HL-A132B, HL-A132C,HL-A133A,HL-A133B,HL-A133C,HL-A134A, HL-A134B,HL-A134C
Hospital Bed	HL-A120A,HL-A120B,HL-A120C,HL-A120D
Pediatric Hospital Bed	HL-A141A,HL-A141B,HL-A141C,HL-A142A,HL-A142B, HL-A142C,HL-A143A,HL-A143B,HL-A143C
Infant Bed	HL-A151A,HL-A151B,HL-A152A,HL-A152B,HL-A153A, HL-A153B
Gynecological Examination Couch	HL-A240A,HL-A240B,HL-A240C
Examination Couch	HL-A161A,HL-A161B,HL-A161C,HL-A162A,HL-A162B, HL-A162C,HL-A162D,HL-A163A,HL-A163B,HL-A163C
Delivery Bed	HL-A231A,HL-A231B,HL-A232A,HL-A232B
Hospital Trolley	HL-A411A,HL-A411B,HL-A412A,HL-A412B
Operating Table	HL-A310A,HL-A310B

ANNEX II

Surgical Positioning Pad	HL-A811series,HL-A812series,HL-A813series,HL-A814series, HL-A815series,HL-A816series,HL-A817series,HL-A818series, HL-A819series,HL-A8110series,HL-A8111series,HL-A8112series, HL-A8113series,HL-A8114series,HL-A8115series,HL-A8116series, HL-A8117series,HL-A8118series,HL-A8119series,HL-A8120series, HL-A8121series,HL-A8122series,HL-A8123series,HL-A8124series, HL-A8125series,HL-A8126series,HL-A8127series,HL-A821series, HL-A822series,HL-A823series,HL-A824series,HL-A825series, HL-A826series,HL-A827series,HL-A828series,HL-A829series, HL-A8210series,HL-A8211series,HL-A8212series,HL-A8213series, HL-A8214series,HL-A8215series,HL-A8216series,HL-A8217series, HL-A8218series,HL-A8219series,HL-A8220series,HL-A8221series, HL-A8222series,HL-A8223series,HL-A8224series,HL-A8225series, HL-A8226series,HL-A8227series,HL-A8228series,HL-A8229series, HL-A8230series,HL-A8231series,HL-A8232series,HL-A8233series, HL-A8234series,HL-A8235series,HL-A8236series,HL-A8237series, HL-A8238series,HL-A8239series,HL-A8240series,HL-A8241series, HL-A8242series,HL-A8243series,HL-A8244series,HL-A8245series, HL-A8246series,HL-A8247series,HL-A8248series,HL-A8249series, HL-A8250series,HL-A8251series,HL-A8252series,HL-A8253series, HL-A8254series,HL-A8255series,HL-A8256series,HL-A8257series, HL-A8258series,HL-A8259series,HL-A8260series,HL-A8261series, HL-A8262series,HL-A8263series
Surgical Lithotomy stirrup Leg Holders	HL-A1101A,HL-A1101B
Lateral Position Fixing System	HL-A1001A,HL-A1001B,HL-A1002A,HL-A1002B
Surgical Head Support	HL-A910A,HL-A910B,HL-A910C
Medical trolley	HL-D421A,HL-D421B,HL-D432A,HL-D432B, HL-D443A,HL-D443B
Medical cabinet	HL-D511A,HL-D511B,HL-D511C,HL-D512A,HL-D512B,HL-D512C
Medical Table	HL-D611A,HL-D611B,HL-D611C,HL-D612A,HL-D612B,HL-D612C
Patient Return Electrode Pad	HL-B1201A,HL-B1201B,HL-B1201C,HL-B1201D
Electric Hospital Bed	HL-B117A,HL-B117B,HL-B115A,HL-B115B
Electric Operating Table	HL-B320A,HL-B320B,HL-B330A,HL-B330B
Electric Delivery Bed	HL-B220A,HL-B221A



REGISTRATION NO. 04719Q10000985

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM FOR MEDICAL DEVICES

This is to certify that the quality management system of

HI-LIFE TECHNOLOGY (HEBEI) CO., LTD

Registered Address: 67.2 km of the south of no.112 highway, bazhou, hebei province, china

Manufacturing Address: 67.2 km of the south of no.112 highway, bazhou, hebei province, china

Has been assessed and conformed to the following standard(s)

YY/T 0287-2017 idt ISO 13485:2016

The certificate is valid for the following scope:

The Design and development, production and service of Manual Hospital Bed, Hospital Bed, Pediatric Hospital Bed, Infant Bed, Gynecological Examination Couch, Examination Couch, Delivery Bed, Hospital Trolley, Operating Table, Surgical Positioning Pad, Surgical Lithotomy stirrup Leg Holders, Lateral Position Fixing System, Surgical Head Support, LDR Obstetric Bed, Electric Hospital Bed, Electric Operating Table.

The Design and development, production and service of Bedside Table, Mattress, IV Stand, Accompanying Chair/ Infusion Chair, Orthopedic traction frame for Medical devices supporting products.

Date of issue: August 27, 2019

Date of expiry: August 26, 2022

Date of change: May 31, 2021

General Manager:

**BEIJING HUA GUANG CERTIFICATION
OF MEDICAL DEVICES CO., LTD.**

Hydraulic Patient Transfer Trolley

HL-A411B



OPERATIONAL MANUAL

Thank you for choosing our latest model of Patient transfer Trolley.

To obtain the best results and maximum benefit, please read this manual before use.

On receipt check the outside box for any damage which may have occurred in transit, and if necessary advise a service manager.

Remove the unit from the cardboard container carefully and check the contents. The patient transfer trolley is fully assembled and ready to use.

Contents of Package:

Patient Transfer Trolley 1 set

I.V. Pole 1 piece

Mattress 1 piece

User Manual 1piece

Contents

Patient transfer trolley.....	1
HL-A411B.....	1
Contents of Package:.....	1
Application:.....	2
Structure:.....	2
Function and main specification:.....	2
Operating Instructions:.....	3
Safety Information:.....	3
Maintenance, Care and Warranty:.....	3
Storage and Transportation Conditions:.....	4
Contacts.....	4

Range of application :

The HL-A411B Hydraulic Patient Transfer Trolley is for use in hospitals, health centres and clinics for patient transferring, patient infusion and examination.

Structure:

The HL-A411B Hydraulic Patient Transfer Trolley consists of base, main frame, bed surface, hydraulic pump, cushioned mattress, side rails, pushing handles, IV pole, four castors with central brake, foot pedals

- Main frame: Mild steel with epoxy coated paint.
- Base: Durable shaped plastic
- Mattress: High density foam filling covered With Tough High Quality Washable Fabrics.
- Castors: Dia. 150mm with central brake
- Adjustment: backrest, height, trendelenburg and reverse trendelenburg

Function and main specification:

- Backrest adjustable angle: 0-75°
- Trendelenburg and reverse Trendelenburg: 15°
- Overall size: L2130mm*W830mm*H630mm/950mm, width of pedal control 700mm, width of side rails 750mm
- Size of lying platform: L910mm*W630mm, height adjustment range: 630mm -950mm
- Maximum loading capacity: 250kg
- IV pole sockets at head and foot sections
- Lying platform adopt high quality Chemical Resistant Laminate for X-ray translucent

- Reliable central locking system, size of castors:150mm, with the fifth guide wheel
- Pushing handles can be hidden

Operating Instructions:

- Central brake foot pedal: one end is for moving action, another end is for braking. Press either with foot, then move the bed, or brake it.
- Steering System: controlling the bed go forward at target direction. Press one end of the pedal to make wheel down to ground, then the bed can go forward at one direction. Press another end of the pedal, then the bed can move at any direction.
- Bed hi-Lo adjustment: press the lift pedal continuously to rise the bed platform. Press the two drop pedal at the same time, to lower the bed platform.
- Bed tilting adjustment: press drop pedal at back section, then lower height of back section. Press drop pedal at leg section, then lower height of leg section.
- Hi-Low adjustment of side rails: pull up the side rails into highest position, then it will lock itself at highest position. Pull the lock of side rails gently, it can go down.
- To lift the back section, pull up the red handle under the back board. To lower it, pull up the red handle, at the same time, press down the back section to target height, then release the handle.
- Put the oxygen bottle on its shelf, and then lock it.

Safety Information:

- Most exposed parts of the bed, are made of plastic, please don't collide them, or touch it with high-temperature objects.
- When pull up the side rails, please be sure it is locked at the highest position and be stable there.
- When using oxygen bottle, be sure it is locked, to avoid it fall down and injury people.

Maintenance, Care and Warranty:

- Warranty: 2 years
- Keep it clean. Clean it with ordinary mundificant instead of chemicals. For disinfection, use cotton to dip Lysol and clean it.
- Maintenance and repairs should only be carried out by a qualified engineer or technician or contact the office (see below) for after sales service and spare parts.
- When the Trolley is not in use it should be stored in a cool dry place.

Storage and Transportation Conditions:

- Storage: The Patient Transfer Trolley is packed in a carton and can be stored in temperatures from -40°C~+55°C, relative humidity less than 80%.
- Transportation: The Patient Transfer Trolley should be transported in its original box. Avoid shaking and heavy impacts. Lift the carton by using the grip holes in the carton.

Hi-Life Technology (Hebei) Co.,Ltd

67.2 KM of the south of No.112 highway, Bazhou, Hebei Province, China

Tel: 0086-22-83717985

Fax: +86 22 83718934

Mobile: 0086-139 2093 6501

Post code: 300384

Website: www.xuhuamedical.com

Manual Patient Transfer Trolley

HL-A411A



OPERATIONAL MANUAL

Thank you for choosing our latest model of Patient transfer Trolley.

To obtain the best results and maximum benefit, please read this manual before use.

On receipt check the outside box for any damage which may have occurred in transit, and if necessary advise a service manager.

Remove the unit from the cardboard container carefully and check the contents. The patient transfer trolley is fully assembled and ready to use.

Contents of Package:

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I.V. Pole 1 piece

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Operating Instructions:.....	3
Safety Information:.....	3
Maintenance, Care and Warranty:.....	3
Storage and Transportation Conditions:.....	4
Contacts.....	4

Range of application :

The HL-A411A Manual Patient Transfer Trolley is for use in hospitals, health centres and clinics for patient transferring, patient infusion and examination.

Structure:

The HL-A411A Manual Patient Transfer Trolley consists of base, main frame, bed surface, mattress, side rails, IV pole, four castors with individual brake, 3 crank handles

- Main frame: stainless steel.
- Mattress: High density foam filling covered With Tough High Quality Washable Fabrics.
- Castors: Dia. 150mm with individual brakes
- Adjustment: height, trendelenburg and reverse trendelenburg

Function and main specification:

- Trendelenburg and reverse Trendelenburg: 15°
- Overall size: L1960mm*W650mm*H650mm/900mm
- Maximum loading capacity: 220kg
- IV pole sockets at head and foot sections
- Size of castors:150mm

Operating Instructions:

- Bed hi-Low adjustment: run the crank handle continuously to rise the bed platform. Run it in the opposite direction to lower the bed platform.
- Bed tilting adjustment: run the crank handle, then lower height of back section. Run another crank handle, then lower height of leg section.

- Hi-Low adjustment of side rails: pull up the side rails into highest position, then it will lock itself at highest position. Pull the lock of side rails gently, it can go down.
- Put the oxygen bottle on its shelf, and then lock it.

Safety Information:

- When pull up the side rails, please be sure it is locked at the highest position and be stable there.
- When using oxygen bottle, be sure it is locked, to avoid it fall down and injury people.

Maintenance, Care and Warranty:

- Warranty: 2 years
- Keep it clean. Clean it with ordinary mundificant instead of chemicals. For disinfection, use cotton to dip Lysol and clean it.
- Maintenance and repairs should only be carried out by a qualified engineer or technician or contact the office (see below) for after sales service and spare parts.
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