

CE Documentation Review



No. 3J191105.SHMSU05

Holder: Shanghai Huifeng Medical Instrument Co., Ltd.

2 Buildings, No. 885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Shadowless Operating Lamp
Model(s): (see the following annex I)

Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 05 November 2019

Expiry date 04 November 2024

Chief Manager
Marco Morina

Deputy Manager
Amanda Farnie

Annex I

No. 3J191105.SHMSU05

Model(s): 700/700LED, 500/500LED, 700W LED, 700S LED, 700E LED, 500WLED, 500S LED, 500E LED, YD02-LED5+5, YD02-LED3+4, YD02-LED4+4, YD02-LED3+3, YD02-LED3, YD02-LED3W, YD02-LED3S, YD02-LED3E, YD02-LED4, YD02-LED4W, YD02-LED4S, YD02-LED4E, YD02-LED3+5, YD02-LED5, YD02-LED5W, YD02-LED5S, YD02-LED5E, YD200C LED, YD200W LED, YD200S LED, YD200E LED, YD02-5LED, YD02-5W LED, YD02-5+5 LED, HF-L25LED, HF-L25C LED, HF-L25C+L25C LED, HF-L25W LED, HF-L25E LED, HF-280LED, HF-280CLED, HF-280WLED, HF-280ELED, HF-FS LED, YD01-4E LED, YD01-4 LED, YD01-5E LED, YD01-5 LED, YD01-4, YD01-4E, YD01-5, YD01-5E, YD01A, YD01AE, YD01W, YD01W LED, YD01A LED, YD01AE LED, YD01-1SA, YD01-SE, YD150LED, YD01-I, YD01-II, YD01-1LED, YD01-1E LED, ZF700/700, ZF700/500, ZF500/500, ZF600/600, ZF600, ZF700, ZF500, ZF700S, ZF700E, ZF600E, ZF600S, ZF500S, ZF500E, ZF500W, ZF600W, ZF700W, YD50(LED), YD300(LED), YD01-LED3, YD01-LED4, YD01-LED5, SY01-LED3, SY01-LED3A, SY02-LED3+5D, SY02-LED3+5D-TV, SY02-LED5+5D, SY02-LED3+3D, SY02-LED3D, SY02-LED5D, YD300 LED, YD300+300LED, YD300E LED, YD300CLED, YD300WLED, 760/760 LED, 760 LED, 760/300LED, YD02-4LED, YD02-4W LED, YD02-4+4 LED



America

CERTIFICATE

No. QS5 061501 0011 Rev. 00

Certificate Holder: Shanghai Huifeng Medical Instrument Co., Ltd.
 Building NO.2, NO.885, Qixing Road, Nicheng Town
 Pudong New Area
 201306 Shanghai
 PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Air Cushions for Bedsores, Shadowless Operating Lamps, Electric-Heating Boiling Disinfectors and Electric Pneumatic Hemostat; Distribution of Operating Table, Pendant and Bedhead Unit

Standard(s): ISO 9001:2015

The Certification Body of TÜV SÜD America Inc. certifies that the company mentioned above has established and is maintaining a quality management system that meets the requirements of the listed standards.

Report No.: SH1811713

Effective Date: 2019-04-17

Expiry Date: 2022-04-16

Page 1 of 1
Date of Issue: 2019-04-26

(Arie Henkin)
 Manager, Certification Body MHS



Certificate

No. Q5 061501 0009 Rev. 01

Holder of Certificate: Shanghai Huifeng Medical Instrument Co., Ltd.

Building NO.2, NO.885, Qiuxing Road, Nicheng Town
Pudong New Area
201306 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):

Shanghai Huifeng Medical Instrument Co., Ltd.
Building NO.2, NO.885, Qiuxing Road, Nicheng Town, Pudong
New Area, 201306 Shanghai, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: Design and Development,
Production and Distribution of
Air Cushions for Bedsore,
Shadowless Operating Lamps,
Electric-Heating Boiling Disinfectors,
Electric Pneumatic Hemostat
Distribution of Operating table,
ICU Pendant and Bedhead Unit

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH1811713

Valid from: 2019-05-01

Valid until: 2022-04-30

Date, 2019-04-15

Stefan Preiß

CE Documentation Review



No. 3J190729.SHMTN80

Holder: Shanghai Huifeng Medical Instrument Co., Ltd.

2 Buildings, No. 885, Qixing Road, Nicheng Town, Pudong New Area, Shanghai, China

Review goal: Verification of the presence of the Technical File in regards of the Medical Devices Directive 93/42/EEC Annex VII

Product: Operating Table, Shadowless Operating Lamp

Model(s): (see the following annex I)

Classification: Class I
(accordingly to the Manufacturer's declaration)

Review output: We attest that a Technical File in reference to the Directive 93/42/EEC is in place for the CE Marking process. This document has been issued on voluntary basis and not as NB. Whereas the Manufacturer is responsible and not exempted to carry out all the necessary activities, as required by the Directive, before placing the CE Mark on the product.

Date of issue 29 July 2019

Expiry date 28 July 2024

Chief Manager
Marco Morina

Deputy Manager
Amanda Pravia

Annex I

No. 3J190729.SHMTN80

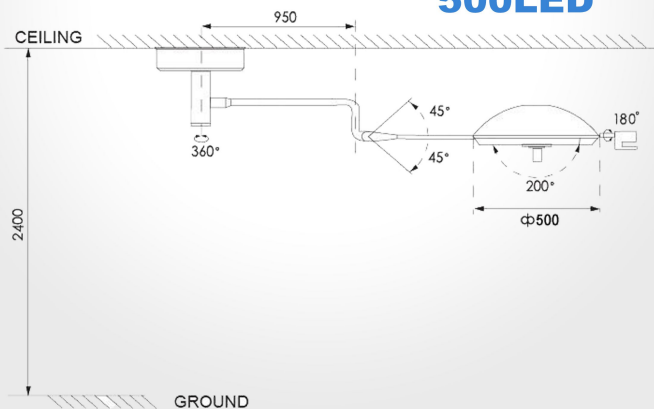
Name	Model/ Type
Operating Table	HFOT99C, HFOT99, HFOT99D, HFEPB99A, HFEPB99B, HFEPB99C, HFEPB99, HFOT99S, HFOT99X, HFOOT99A
Shadowless Operating Lamp	SY02-LED3+5, SY02-LED3, SY02-LED5, SY02-LED5+5, SY02-LED3+5-TV, SY02-LED5+5-TV, SY02-LED3+3, HF-L3+4CLED, HF-L4+4CLED, HF-L3+3CLED, HF-L4CLED, HF-L3CLED, HF-L4WLED, HF-L3WLED, HF-L4SLED, HF-L3SLED, HF-L4ELED, HF-L3ELED, 700/500LED, 700LED, 500LED





INSTALLATION DIAGRAM

500LED



500LED

Adjustable color temperature

Through reliable beam synthesis control technology, the color temperature can be adjusted between 3800K-5000K under the condition that the color rendering index is 93. Surgeons can adjust the color temperature according to their own habits or different surgical sites to achieve the ideal tissue contrast and achieve the best tissue resolution.



700/500LED one key low light (Endoscope)

The operation shadowless lamp is equipped with a one-key low light (endoscope) lighting mode, which is convenient for the surgeon to quickly switch from the general mode. It does not interfere with the doctor's field of vision and the observation of tissues during endoscopic surgery.



General mode

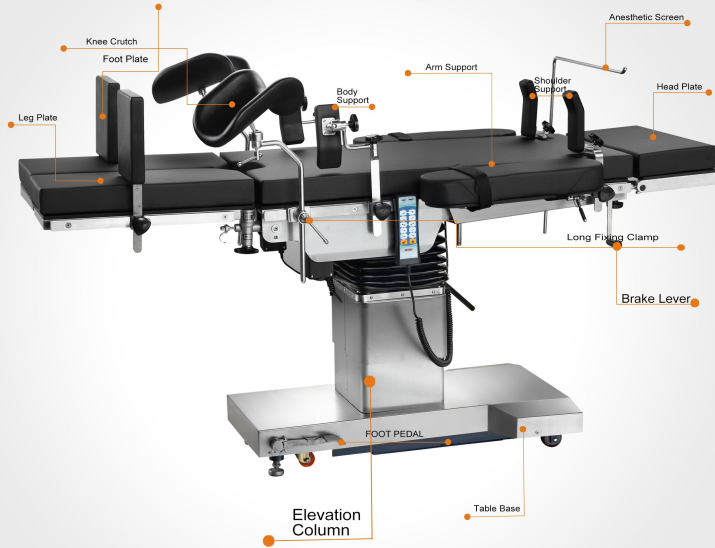
700LED Endoscope Mode

500LED Endoscope Mode

Main Technical Data

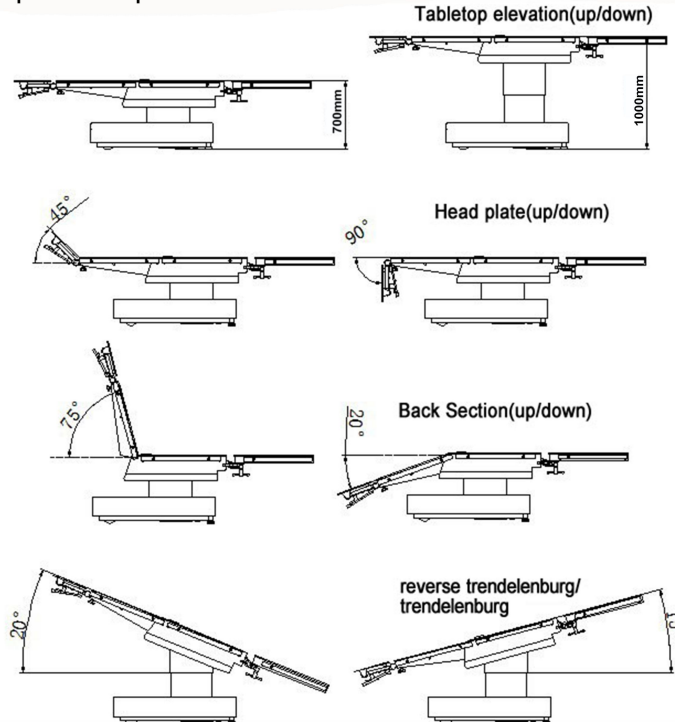
500LED <small>Adjust Color Temperature</small>	
Illuminance	≥140,000Lux
Colour temperature	3800±500K 4400±500K 5000±500K
Colour reduction index(Ra)	95
Total irradiance	534W/m ²
Size of light field	250-300mm
Service life of illuminant	50,000h
Power supply voltage	AC110-240V 50/60Hz
Lowest height of installation	2900mm
Total power consumptio	60W
Total LED bulb quantity	72 pcs (12*6)
Illuminance depth	≥1400mm
LED bulb	3.3mW/m ² lx
ENDO	YES





HFEOT99

HFEOT99
operation position sketch



Main Technical Data

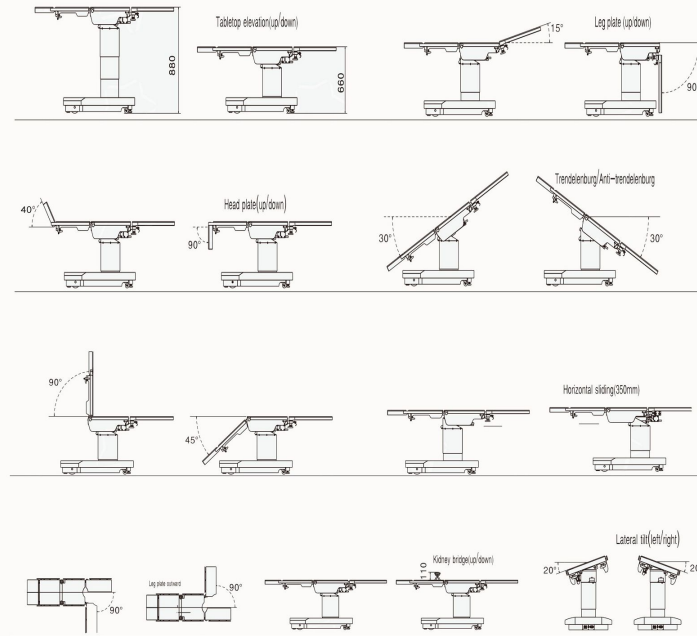
HFEOT99		Manual Hydraulic Operating table
Tabletop Length	2070mm	
Tabletop Width	550mm	
Elevation (down/up)	700/1000mm	
Trendelenburg/Reverse Trendelenburg	25°/25°	
Lateral Tilt(left/right)	15°/15°	
Head Rest(up/down)	45°/90°	
Foot Plate(up/down&) Horizontal Positioning	15°/90°/90°	
Back Plate(up/down)	75°/20°	
Kidney Bridge	110mm	
Longitudinal Sliding	300mm	
Power	220V 50Hz 1.0kW	





HFEOT99C

HFEOT99C
operation position sketch



Main Technical Data

HFEOT99C Manual Hydraulic Operating table	
Tabletop Length	1970mm
Tabletop Width	500mm
Elevation (down/up)	690/1100mm
Trendelenburg/Reverse Trendelenburg	30°/30°
Lateral Tilt(left/right)	20°/20°
Head Rest(up/down)	40°/90°
Foot Plate(up/down&) Horizontal Positioning	15°/90°/90°
Back Plate(up/down)	90°/40°
Longitudinal Sliding	350mm
Power	220V 50Hz 1.0kW
Kidney bridge elevation	110mm

