

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



Certificate

No. Q5 061501 0009 Rev. 02

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

See Scope of Certificate

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, ICU Pendant and Bedhead Unit, Patient monitor, Oxygen concentrator

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:Q5 061501 0009 Rev. 02

Report No.: SH2111702

Valid from: 2022-05-01

Valid until: 2025-04-30

Date, 2022-04-25

Christoph Dicks
Head of Certification/Notified Body



Fiscal Year 2022 USA FDA CERTIFICATION OF REGISTRATION

This certifies that:

Shanghai Huifeng Medical Instrument Co., Ltd.

**Building 2, No. 885, Qiuxing Road, Nicheng Town, Pudong New Area,
Shanghai, 201311, China**

has completed the FDA Establishment Registration (as contract manufacturer) and
Device Listing with the US Food & Drug Administration, through

MicroKy Services, LLC.

Registration Number: 3008610343

Owner/Operator Number: 10048425

Device Listings:

Listing Number:	D234483
Premarket Submission Number/Type:	510(k) Exempt
Product Code(s):	FTD
Device Name(s):	LAMP, SURGICAL
Activities:	Contract Manufacturer

To be continued

MicroKy Sevices, LLC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. MicroKy Services, LLC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. MicroKy Services, LLC assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, MicroKy Services, LLC is not affiliated with the U.S. Food and Drug Administration.



MicroKy Services, LLC

Executive Director

Issued: Nov. 05, 2021

Cert. No.: 2021110501

Expiration Date: Dec. 31, 2022

Continued from previous page

Proprietary Names:

500/500LED, 500E LED, 500LED, 500S LED, 500WLED, 700/500LED, 700/700LED, 700E LED, 700LED, 700S LED, 700W LED, 760 LED, 760/300 LED, 760/760 LED, HF-280CLED, HF-280ELED, HF-280LED, HF-280WLED, HF-FS LED, HF-L25C LED, HF-L25C+L25C LED, HF-L25E LED, HF-L25LED, HF-L25W LED, HF-L3+3CLED, HF-L3+4CLED, HF-L3CLED, HF-L3ELED, HF-L3SLED, HF-L3WLED, HF-L4+4CLED, HF-L4CLED, HF-L4ELED, HF-L4SLED, HF-L4WLED, SY01-LED3, SY01-LED3A, SY02-LED3, SY02-LED3+3, SY02-LED3+3D, SY02-LED3+5, SY02-LED3+5D, SY02-LED3+5D-TV, SY02-LED3+5-TV, SY02-LED3D, SY02-LED5, SY02-LED5+5, SY02-LED5+5D, SY02-LED5+5-TV, SY02-LED5D, YD01-1E LED, YD01-1LED, YD01-1SA, YD01-4, YD01-4 LED, YD01-4E, YD01-4E LED, YD01-5, YD01-5 LED, YD01-5E, YD01-5E LED, YD01A, YD01A LED, YD01AE, YD01AE LED, YD01-I, YD01-II, YD01-LED3, YD01-LED4, YD01-LED5, YD01-SE, YD01W, YD01W LED, YD02.5, YD02-4 LED, YD02-4+4 LED, YD02-4W LED, YD02-5+5 LED, YD02-5LED, YD02-5W LED, YD02-LED3, YD02-LED3+3, YD02-LED3+4, YD02-LED3+5, YD02-LED3E, YD02-LED3S, YD02-LED3W, YD02-LED4, YD02-LED4+4, YD02-LED4E, YD02-LED4S, YD02-LED4W, YD02-LED5, YD02-LED5+5, YD02-LED5E, YD02-LED5S, YD02-LED5W, YD150LED, YD200C LED, YD200E LED, YD200S LED, YD200W LED, YD300 LED, YD300(LED), YD300+300LED, YD300CLED, YD300E LED, YD300WLED, YD50(LED), ZF500, ZF500/500, ZF500E, ZF500S, ZF500W, ZF600, ZF600/600, ZF600E, ZF600S, ZF600W, ZF700, ZF700/500, ZF700/700, ZF700E, ZF700S, ZF700W

MicroKy Sevices, LLC will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. MicroKy Services, LLC makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. MicroKy Services, LLC assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, MicroKy Services, LLC is not affiliated with the U.S. Food and Drug Administration.



MicroKy Services, LLC

A handwritten signature in black ink that appears to read 'Alexander'.

Executive Director

Issued: Nov. 05, 2021

Cert. No.: 2021110501

Expiration Date: Dec. 31, 2022