



DAkkS

Deutsche  
Akkreditierungsstelle  
D-ZM-11321-01-00

Product Service

# Certificate

No. Q5 061501 0009 Rev. 02

**Holder of Certificate:** Shanghai Huifeng Medical Instrument Co., Ltd.Building NO.2, NO.885, Qiuxing Road, Nisheng 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, Nisheng 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 HemostatDistribution 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](http://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,** 2022-04-25Christoph 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 manufacturer, contract manufacturer and foreign exporter) and Device Listing with the US Food & Drug Administration, through MicroKy Services, LLC.

**Registration Number: 3008610343**

**Owner/Operator Number: 10048425**

### Device Listings:

Listing Number	Product Code	Device Name	Premarket Submission Type
D468314	FWX	<b>TABLE, OPERATING-ROOM, MECHANICAL</b> ➤ Manual Hydraulic Operating Table: MT600, HFMH3008A, HFMH3008D, HFMH3008AB, HFMS3001B, HFMH700A, HFMH700AB, HFMPB06A, HFMPB06B, HFMPB06C, HFOOT99, HF201A, HF201C, HF201B, HF201D, HF202A, HF202B	510(k) Exempt
D468315	GDC	<b>TABLE, OPERATING-ROOM, ELECTRICAL</b> ➤ Electric Operating Table: HFEOT99C, HFEOT99X, HFEOT99, HFEOT2000, HFEOT99D, HFEOT99S, HFEOT100, HFEPB99B, HFEPB99D, HFOOT99A, HFOOT99A-1, HF-2000J, HFEOT2000E, HFEPB99A, HF203A, HF203H, HF203F, HF203Q, HF203D, HF203M, HF203E, HF203I, HF204-1G, HF204-1R, HF204-1B, HF204-1D, HF204-8, HF204-Q, HF205-7A, HF205-7, HF205-1A, HF205-1B, HF205-2A, HF205-2B, HF205-12E, HF205-12D, HF205-3A, HF204-A	510(k) Exempt
D468488	HST	<b>APPARATUS, TRACTION, NON-POWERED</b> ➤ Orthopaedics Traction Frame: 1005, 1006, 1007	510(k) Exempt

*MicroKy Services, 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

*Alexander*

Executive Director  
Issued: Mar. 11, 2022  
Cert. No.: 2022031101  
Expiration Date: Dec. 31, 2022



Fiscal Year 2022 USA FDA  
CERTIFICATION OF REGISTRATION

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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

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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

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