Review Report – 审查报告 – 검토 보고서 – Rapport d'Evaluation

CE Documentation Review

No. 3J190729.SHMTN80

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: 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

Digitally signed by Jighili Tatiana
Date: 2021.07.01 12:56:14 EEST
Reason: MoldSign Signature
Location: Moldova

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Annex I

No. 3J190729.SHMTN80

Name	Model/ Type
Operating Table	HFEOT99C, HFEOT99, HFEOT99D, HFEPB99A, HFEPB99B, HFEPB99C, HFEPB99, HFEOT99S, HFEOT99X, 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

Review Report –审查报告–검토 보고서– Rapport d'Evaluation

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
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Deputy Manager
Amanda Haiyue

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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

SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

VERIFICATION OF COMPLIANCE

Verification No.:	SHEM200900799001HSC
Applicant:	SHANGHAI HUIFENG MEDICAL INSTRUMENT CO., LTD.
Address of Applicant:	Building No.2, No.885, Qiuxing Road, Nicheng Town, Pudong New Area, Shanghai, China
Product Description:	UV Sterilizer
Model No.:	HF-YZW110SWII, HF-YZW60SWI, HF-YZW60SWII, HF-YZW110SWI

Sufficient samples of the product have been tested and found to be in conformity with

Test Standards:	EN 55014-1:2017
	EN IEC 61000-3-2:2019
	EN 61000-3-3:2013+A1:2019
	EN 55014-2:2015

As shown in the

Test Report Number(s): SHEM200900799001

This verification of EMC Compliance has been granted to the applicant based on the results of the tests, performed by laboratory of SGS-CSTC Standards Technical Services Co., Ltd. on the sample of the above-mentioned product in accordance with the provisions of the relevant specific standards under Directive 2014/30/EU. The CE mark as shown below can be used, under the responsibility of the manufacturer, after completion of an EU Declaration of Conformity and compliance with all relevant EU Directives.

CE

Parlam Zhan
E&E Section Manager

Date: 2020-09-30

Member of SGS Group (Société Générale de Surveillance)

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

America

CERTIFICATE

No. QS5 061501 0011 Rev. 00

Certificate Holder: **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 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**

Date of Issue: 2019-04-26

(Arie Henkin)
Manager, Certification Body MHS

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D-ZM-11321-01-00

Product Service

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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