





## 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 Bedsore, 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,

ш

7

2022-04-25

Christoph Dicks

Head of Certification/Notified Body

ш

7







## CERTIFICATE

No. QS5 061501 0011 Rev. 02

**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, UV Sterilizer; Distribution of Operating Table, ICU Pendant and Bedhead Unit, Patient Monitor, Oxygen Concentrator

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.:

SH2111702

**Effective Date:** 

2022-04-26

**Expiry Date:** 

2025-04-16

Page 1 of 1

Date of Issue: 2022-05-03

-4gr\_\_\_

(Renee Walker)

Manager, US Certification Body,

Medical and Health Services

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com

TUV®