



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q6 110907 0001 Rev. 01

Holder of Certificate: **Shanghai Shiyin Photoelectric Instrument Co., Ltd.**

Building 60, No. 1-159, Lane 193
Nanlu Road, Xuanqiao Town
Pudong New Area
201300 Shanghai
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of Medical portable endoscopy unit, Medical endoscopy camera system, Medical 4K UHD endoscopy camera system and Medical LED cold light source**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q6 110907 0001 Rev. 01

Report No.: SH24172001

Valid from: 2025-04-07

Valid until: 2028-04-06

Date, 2025-02-10

Christoph Dicks

Head of Certification/Notified Body



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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies):

Shanghai Shiyin Photoelectric Instrument Co., Ltd.
Building 60, No. 1-159, Lane 193, Nanlu Road, Xuanqiao Town,
Pudong New Area, 201300 Shanghai, PEOPLE'S REPUBLIC OF
CHINA

Distribution of Medical portable endoscopy unit, Medical endoscopy
camera system, Medical 4K UHD endoscopy camera system and
Medical LED cold light source

Anhui Shiyin Photoelectric Instrument Co., Ltd.

5th Floor, 10 # F, 100 Shunhe Road, Longcheng Town, Xiao County,
235200 Suzhou, Anhui Province, PEOPLE'S REPUBLIC OF CHINA

Production and Distribution of Medical endoscopy camera system,
Medical 4K UHD endoscopy camera system and Medical LED cold
light source

Anhui Youtak Medical Technology Co., Ltd

1st, 2nd, and 3rd floors, 10 # F, 100 Shunhe Road, Longcheng
Town, Xiao County, 235200 Suzhou, Anhui, PEOPLE'S REPUBLIC
OF CHINA

Production and Distribution of Medical portable endoscopy unit,
Medical endoscopy camera system, Medical 4K UHD endoscopy
camera system and Medical LED cold light source