

EU DECLARATION OF CONFORMITY

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

Manufacturer: Shanghai Shiyin Photoelectric Instrument Co., Ltd.
Building 60, No. 1-159, Lane 193, Nanlu Road, Xuanqiao
Town, Pudong New Area, Shanghai, P.R. China. Post Code:
201300

Trademark: 

SRN: CN-MF-000025800

European Representative: Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherland

SRN: NL-AR-000002066

Trade name: Medical Endoscope Camera System,
4K Medical Endoscope Camera System,
Medical LED Cold Light Source

Product name: Medical Endoscope Camera System,
4K Medical Endoscope Camera System,
Medical LED Cold Light Source

Product code / Catalogue number: Model: SY-SHREK-7812(Product Code: SY-GW800C-N),
Model: SY-SHREK-7815(Product Code: SY-GW900C-N),
Model: SY-SHREK-7817(Product Code: SY-GW1000C-N),
Model: SY-SHREK-7818(Product Code: SY-GW1100C-N),
Model: SY-SHREK-UHD907(Product Code:
SY-GW1200C-A), Model: SY-SHREK-UHD909(Product
Code: SY-GW1200C-N),
Model: SY-SHREK-7712(Product Code: SY-GW800L-N),
Model: SY-SHREK-7717(Product Code: SY-GW1000L-N),
Model: SY-SHREK-7718(Product Code: SY-GW1200L-N)

Basic UDI-DI: SY-SHREK-7812: 697540840SY-SHREK-78121DK
SY-SHREK-7815: 697540840SY-SHREK-78151DU
SY-SHREK-7817: 697540840SY-SHREK-78171E2
SY-SHREK-7818: 697540840SY-SHREK-78181E5
SY-SHREK-UHD907: 697540840SY-GW1200C-A114S
SY-SHREK-UHD909: 697540840SY-GW1200C-N116T
SY-SHREK-7712: 697540840SY-SHREK-77121DC
SY-SHREK-7717: 697540840SY-SHREK-77171DT
SY-SHREK-7718: 697540840SY-SHREK-77181DW

Classification acc. to MDR Class I, rule 13
Ax. VIII:

Applied Standard & Common Specification: EN 60601-1:2006+A12:2014+EN 60601-1-2:2015+A1:2021

Conformity assessment procedure: Annex II + Annex III of MDR

CE certificate No.: N.A.

Name and ID of the Notified N.A.

Body:

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

Signature: Yan Liu

Title: General Manager

Position: Building 60, No.1-159, Lane 193, Nanlu Road, Xuanqiao Town, Pudong New Area, Shanghai, P.R. China.

Date: 24/04/2022