Declaration — Декларация — Declaración — إعلان

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: SHREK

SRN: CN-MF-000025800

Digitally signed by Jighili Tatiana
Date: 2025.07.09 10:50:47 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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)
Model: SY-SHREK-UHD1210(Product Code: SY-GW1210C)
Model: SY-SHREK-UHD1220(Product Code: SY-GW1220C)
Model: SY-SHREK-1200(Product Code: SY-GW1210L)

Declaration — Декларация — Declaración — إعلان

CE

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 SY-SHREK-UHD1210: 697540840SY-GW1210C00003B SY-SHREK-UHD1220: 697540840SY-GW1220C00003U SY-SHREK-1200: 697540840SY-SHREK-120009S
Classification acc. to MDR Ax. VIII:	Class I, rule 13
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 Body:	N.A.

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.
Eff. Date:	19/04/2023
Exp. Date:	18/04/2028

SHANGHAI SHIYIN PHOTOELECTRIC INSTRUMENT CO., LTD. 上海世音光电仪器有限公司