DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards
EN ISO 14971:2019+A11:2021
EN ISO 15223-1:2021+A1:2025
EN ISO 20417:2021
EN 60601-1-2:2015+A1:2021
EN 60601-1:2006+A13:2024
EN IEC 60601-2-41:2021

Remark
The declaration of conformity is valid in connection with the release technical document MDR-TCF-002
All the supporting documentation is retained at the premises of the manufacturer.
The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.
File No.: MDR-TCF-002-08

Manufacturer

Name: Shantou Easywell Electronic Technologies Co.,Ltd.
Address: 5th Floor and No.1 West Side of 6th Floor, H5 Industrial Building, No.16 Lianjiang Road,Longhu District,Shantou,China
SRN: CN-MF-000016725

Product Information

Name: Medical Lights
Model: See Annex
EMDN: Z120107
Basic UDI-DI: See Annex 5
Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Date:2026.03.15

Position: GM Place: Shantou/China

Annex

Name	Model	Basic UDI
Medical Lights	KS-200、KS-2020、KS-Q10-03A、KS-Q10-03LB、KS-Q10-03C、KS-Q10-03W、KS-Q10-02A、KS-Q10-02B、KS-Q10-02LB、KS-Q10-02C、KS-Q10-02W、KS-Q10-02R、KS-1088、KS-1088U	697447153ML-01GG
	KS-Q7-02C、KS-Q7-02A、KS-Q7-02LB、KS-Q7-02W、KS-Q7-02R、KS-Q7、KS-Q7LB、KS-Q7E、KS-Q6、KS-Q6LB、KS-Q6B、KS-Q6D、KS-Q6S、KS-LA-6D、KS-LA-6S、KS-LA-6B	697447153ML-02GJ
	KS-Q5、KS-Q5-3D、KS-Q5-3S、KS-Q5-3B、KS-Q5N、KS-Q5N-3D、KS-Q5N-3S、KS-Q5N-3B、KS-Q3、KS-Q3B、KS-Q3D、KS-Q3S、KS-Q35、KS-Q50、KS-ID、KS-RE01、KS-RE01-3D、KS-RE01-3S、KS-RE01-3B	697447153ML-03GL
	KS-1081D、KS-1082B、KS-WL16、KS-CM2012S、KS-IP48、KS-IP48BT、KS-LA-6P、KS-H05、KS-W01、KS-W02、KS-R01、KS-MC01、KS-H1N、KS-H2N、KS-D01、MST-4000I、MST-4000II、MST-4000III、MST-4000IV、MST-PH、MST-PX、MST-PL,KS-H8,KS-IR275	697447153ML-04GN

SHANTOU EASYWELL ELECTRONIC TECHNOLOGIES CO., LTD.
汕头市易维电子科技有限公司
4405075023030