EU DECLARATION OF CONFORMITY

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

Manufacturer:	Shantou Easywell Electronic Technologies Co.,Ltd 5th Floor and No.1 West Side Of 6th Floor, H5 Industrial Building, No.16 Lianjiang Road,Longhu Distric,Shantou, China
Trademark:	Easywell
SRN	CN-MF-000016725
European Representative:	Kingsmead Service B.V. Zonnehof 36, 2632 BE, Nootdorp, Netherland
SRN	NL-AR-000002066
Trade name:	Medical Light
Product name:	Medical Light
Product code / Catalogue number:	KS-H1N, KS-W03, KS-Q3, KS-Q7, KS-Q7E, KS-Q5-5D
Basic UDI-DI	697447153012LB / 697447153083M2 / 697447153001L6 / 697447153005LE/ 697447153085M6 / 697447153084M4
Classification acc. to MDR Ax. VIII:	Class I, rule 13
Applied Standard & Common Specification:	EN ISO 14971:2019/A11:2021, EN ISO 20417:2021, EN 60601-1:2006+A1:2013, EN 60601-1-2:2015, EN 60601-2-41:2009
Conformity assessment procedure:	Annex II + Annex III of MDR

Intended Use: KS medical lamp is designed for the partial spot illumination during the medical examination and minor operation, it mainly applies for dental, hospital out-patient, etc.

We, the manufacturer, herewith declare the compliance with Directive 2011/65/UE + DELEGATED DIRECTIVE (EU) 2015/863

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.

SHANTOU EASYWELL ELECTRONIC TECHNOLOGIES CO.,LTD 0507502303O

Justin Liu,
General Manager

Shantou City, Guangdong Province, China 16. 01. 2024