

# 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-LA-6D

**Basic UDI-DI** 697447153008LL

**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.

  
Justin Liu,  
General Manager

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