

# EU DECLARATION OF CONFORMITY

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

**Manufacturer:** Shantou Easywell Electronic Technologies Co.,Ltd  
NO.1 West side of 6th Floor H5 Industrial Building, No. 16  
Lianjiang Road,Longhu district,Shantou,China(515041)

**Trademark:** Easywell

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

**SRN** NL-AR-000002066

**Trade name:** Medical lights

**Product name:** Medical lights

**Product code / Catalogue number:** KS Series, MST Series, SL Series, LED Series

**Basic UDI** 697447153000L4 / 697447153001L6/  
697447153004LC

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

**Applied Standard & Common Specification:** EN ISO14971:2012 , EN1041:2008, EN60601-1:2006+A1:2013, EN60601-1-2:2015, EN60601-2-41:2009

**Conformity assessment procedure:** Annex II + Annex III of MDR

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 10. 03. 2021