

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/697447153008LL

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