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:	LED Phototherapy Light
Product name:	LED Phototherapy Light
Product code / Catalogue number:	KS-IP48
Basic UDI	697447153064LW
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

Intended Use: It is used for the treatment of jaundice caused by excessively high blood bilirubin concentration in newborns caused by pathological and/or physiological factors.

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. 汕头市显维电子科技有限公司 0507502303O

Justin Liu,
General Manager

Shantou City, Guangdong Province, China 10. 03. 2023