



飛宏科技股份有限公司

PHIHONG TECHNOLOGY CO., LTD.

## UK Declaration of Conformity

Manufacturer Name: **Phihong Technology Co., Ltd.**

Manufacturer Address: **No. 568, Fuxing 3rd Rd., Guishan District, Taoyuan City, 333 Taiwan**

Product Name: **Open Frame Medical Power Supply \*(Same as CB cert. )**

Model Name: **PML065-xxxyyy, xxx = 120, 150, 180, 190, 240 or 480 to denote different**

The object of the declaration described is in conformity with the relevant UK

Legislation:

**The Medical Devices Regulations 2002 (S.I. 2002/618)**

**Electromagnetic Compatibility Regulations (S.I. 2016/1091)**

**The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations (S.I. 2012/3032.)**

References to the relevant designated standards used, including the date of the specification, in relation to which conformity is declared:

**EN 60601-1:2006+A11+A1+A12**

**IEC 60601-1-2: 2014 (Ed 4.0); EN 60601-1-2: 2015**

**EN 55011: 2016 + A1:2017**

**EN 61000-4-2: 2009, EN 61000-4-3: 2006 + A2: 2010**

**EN 61000-4-4: 2012, EN 61000-4-5: 2014, EN 61000-4-6: 2014**

**EN 61000-4-8: 2010, EN 61000-4-11: 2004,**

**EN 61000-3-2: 2014, EN 61000-3-3: 2013**

**RoHS (Recast) EN IEC 63000: 2018**



Base on the above conformity, the product is tagged with the following symbol:

Person responsible for making this declaration:

Name, Surname: **Shirley, Hsu**

Legal Signature:

Title : **Compliance Manager**

Place: **US Branch**

Date: **13-April-2022**