飛宏科技股份有限公司
PHIHONG TECHNOLOGY CO., LTD.

EU 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**

This declaration of conformity is issue under the sole responsibility of the manufacturer
The object of the declaration described above is in conformity with the relevant Union Harmonization legislation:

EMC Directive 2014/30/EU
RoHS Directive 2011/65/EU (+Approved Directive (EU)2017/2102)
MIDR Regulation (EU)2017/745

is herewith confirmed to comply with the essential requirements and provisions of Council Directive concerning medical devices (93/42/EEC), which the evaluation regarding Council Directive concerning medical devices (93/42/EEC), the following standards are applied:

EN 60601-1:2006+A11+A1+A12
IEC 60601-1-2: 2014 (Ed 4.0); EN 60601-1-2: 2015
EN 55011: 2009 + A1
EN 61000-4-2: 2009, EN 61000-4-3: 2006 + A1: 2008 + 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: CE

Person responsible for making this declaration:
Name, Surname: **Shirley, Hsu**
Title : **Compliance Manager**
Place: **US Branch**
Date:**13-April-2022**

Legal Signature: