



全漢企業股份有限公司

## 安規證書

料號 :  
Model Name FSP400-70MPE,NI-400MPE,TMPC-400E  
版次 : 07  
文件編號 : SFD16065135-R1  
作者 : chow/周懿慧(FSP)  
SFA NO. : SFA23121049  
Trade mark : FSP,TRUMPower  
安規種類 : EMC/醫療類  
發行日期 : 2024/02/05 15:12:42  
備註 : EMC 醫療類 4.1 for FSP400-70MPE series 增加型號



# Technical Compliance Statement

## EMC Test Report

For the following information

Ref. File No.: C1M2401054

Product : Switching Power Supply  
Model Name : (1)FSP400-70MPE (2)NI-400MPE (3)TMPC-400E  
Brand Name : (1)~(2)FSP (3)TRUMPower  
Applicant : FSP Group Inc.  
Standards :  
EN 60601-1-2:2015 +A1:2021 (IEC 60601-1-2:2014 +AMD:2020)(Edition 4.1)  
BS EN 60601-1-2:2015 +A1:2021  
Emission: CISPR 11:2015 +A1:2016 +A2:2019, Class B  
EN 55011:2016 +A11:2020  
EN IEC 61000-3-2:2019+A1:2021 (IEC 61000-3-2:2018 +A1:2020),  
BS EN IEC 61000-3-2:2019+A1:2021 and  
EN 61000-3-3:2013 +A1:2019 (IEC 61000-3-3:2013 +A1:2017),  
EN 61000-3-3:2013 +A1:2019 +A2:2021  
(IEC 61000-3-3:2013 +A1:2019 +A2:2021)  
BS EN 61000-3-3:2013 +A1:2019,  
BS EN 61000-3-3:2013 +A1:2019 +A2:2021  
Immunity: IEC 61000-4-2:2008, IEC 61000-4-3:2020  
IEC 61000-4-4:2012, IEC 61000-4-5:2014+A1:2017,  
IEC 61000-4-6:2013, IEC 61000-4-8:2009,  
IEC 61000-4-11:2020

We hereby certify that the above product has been tested by us with the listed standards and found in compliance with the Regulation (EU) 2017/745 concerning medical device. The test data and results are included in the test report **EM-E160711C**.

Signature



Alex Deng/Deputy Manager  
Date: 2024. 01. 10

Test Laboratory:  
Audix Technology Corporation, EMC Department  
TAF Accreditation No.: 1724  
Web Site: [www.audixtech.com](http://www.audixtech.com)

The statement is based on a single evaluation of one sample of the above-mentioned products. It does not imply an assessment of the whole production and does not permit the use of the test lab logo.