

FSP Technology Inc., Kaohsiung Branch

2-3, EAST 3RD STREET, N.E.P.Z., P.O. BOX. 32-25, KAOHSIUNG, TAIWAN, R. O. C. ISO 9001 Certified

DECLARATION OF CONFORMITY (DoC)

Object of the declaration: External Power Supply

Family Name:

PMP400 series

Model Number:

PMP400-x-S; Where x = 13-1, 14, 15, 17, 18;

The above mentioned product complies with the essential protection requirements of European Council Directive and standards used for this declaration are as follows:

93/42/EEC

IEC 60601-1:2005/A1:2012

(Medical Devices Directive) (EN 60601-1:2006/A1:2013)

Medical electrical equipment -- Part 1: General

requirements for basic safety and essential performance

IEC 60601-1-2: 2014

Medical electrical equipment -- Part 1-2: General

requirements for basic safety and essential performance -

Collateral standard: Electromagnetic compatibility -

Requirements and tests

2011/65/EU

EN50581:2012

(RoHS Directive)

Technical documentation for the assessment of electrical and electronic products with respect to the restriction of

hazardous substances

For use only in or with complete medical equipment where the acceptability of the combination is responsibility by manufacturer of the end-product.

Name of the Manufacturer:

FSP Technology Inc., Kaohsiung Branch

Address of the Manufacturer: 2-3, East 3rd Street, N.E.P.Z., P.O. Box. 35-25

Kaohsiung, Taiwan

The undersigned, hereby declare that the equipment specified above conforms to the above Directive(s) and Standard(s)

13 September 2017	Luce Chen	
(Date)	(Signature)	
Kaohsiung, Taiwan	Bruce Chen, President	
(Place)	(Full Name, Position)	