

Declaration of Conformity

Ref No: EISBG -102P-201910007-CE

Manufacturer name: Delta Electronics, Inc.

Add: 3, Tungyuan Road, Chungli Industrial Zone, Taoyuan City 32063, Taiwan

Tel: 886- 3- 4526107

Fax: 886 -3- 4527314

Is herewith confirmed the following equipment

Product: AC/DC MEDICAL ADAPTER

Brand name: DELTA

Type Designation: MEA-065A12C, MEA-065A15C, MEA-065A19C, MEA-065A24C

Input Rating: 100-240Vac, 1.5-0.75A, 50-60 Hz

Output rating: 12V/5A (for MEA-065A12C); 15V/4.33A (for MEA-065A15C); 19V/3.42A (for MEA-065A19C); 24V/2.71A (for MEA-065A24C)

Comply with the following directives and requirements set out in the Council Directive on the Approximation for the Laws of the Member States

- Low Voltage Directive 2014/35/EU
 - EN 62368-1:2014+A11:2017
- MDR Regulation 2017/745
 - EN 60601-1: 2006/A1 :2013/A12 :2014
 - EN 60601-1-2: 2015
 - CISPR 11:2009+A1:2010 (Group I, Class B)
 - IEC 61000-3-2: 2014
 - IEC 61000-3-3: 2013
- EMC Directive 2014/30/EU
 - EN 55032 : 2012+AC :2013 Class B
 - EN 55032 : 2015+AC :2016 Class B
 - EN 55032 : 2015+A11 :2020 Class B
 - EN 55035 : 2017
 - EN 55035 : 2017+A11 :2020
 - EN 55024 : 2010
 - EN 61000-3-2 : 2014
 - EN IEC 61000-3-2 : 2019
 - EN 61000-3-3 : 2013
 - EN 61000-3-3 : 2013+A1:2019
 - IEC 61000-4-2 : 2008: Edition 2.0
 - IEC 61000-4-3 : 2010: Edition 3.2

- IEC 61000-4-4 : 2012: Edition 3.0
- IEC 61000-4-5 : 2014 : Edition 3.1
- IEC 61000-4-6 : 2013: Edition 4.0
- IEC 61000-4-8 : 2009: Edition 2.0
- IEC 61000-4-11 : 2017: Edition 2.1
- RoHS Directive 2011/65/EU+ (EU) 2020/659
- EN IEC 63000:2018
- Commission Regulation (EU) 2019/1782, ErP Directive 2009/125/EC
- EN 50563: 2011+A1: 2013

This declaration of conformity is issued under the sole responsibility of the manufacturer.


Person responsible for making this declaration

Name, Surname: Sam Tien

Title: Principal Engineer

Place: Taiwan

Date: 2021-06-04

Signature: 

UKCA Declaration of Conformity

Ref No: EISBG -102P-201910007-UKCA

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Tel: 886- 3- 4526107

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On 1 January 2021 the UK standards will be the same in substance and with the same reference as the standards used in the EU. However, they will use the prefix 'BS' to indicate that they are standards adopted by the British Standards Institution as the UK's national standards body.

The UK regulations that correspond to the EU directives are as linked.

- Electrical Equipment (Safety) Regulations 2016
 - BS EN 62368-1:2014+A11:2017
- Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)
 - BS EN 60601-1: 2006/A1 :2013/A12 :2014
 - BS EN 60601-1-2: 2015
 - CISPR 11:2009+A1:2010 (Group I, Class B)
 - IEC 61000-3-2: 2014
 - IEC 61000-3-3: 2013
- Electromagnetic Compatibility Regulations 2016
 - BS EN 55032 : 2012+AC :2013 Class B
 - BS EN 55032 : 2015+AC :2016 Class B
 - BS EN 55032 : 2015+A11 :2020 Class B
 - BS EN 55035 : 2017
 - BS EN 55035 : 2017+A11 :2020
 - BS EN 55024 : 2010
 - BS EN 61000-3-2 : 2014
 - BS EN IEC 61000-3-2 : 2019
 - BS EN 61000-3-3 : 2013

- BS EN 61000-3-3 : 2013+A1:2019
- IEC 61000-4-2 : 2008: Edition 2.0
- IEC 61000-4-3 : 2010: Edition 3.2
- IEC 61000-4-4 : 2012: Edition 3.0
- IEC 61000-4-5 : 2014 : Edition 3.1
- IEC 61000-4-6 : 2013: Edition 4.0
- IEC 61000-4-8 : 2009: Edition 2.0
- IEC 61000-4-11 : 2017: Edition 2.1
- The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012 (as amended 2019,2020)
 - BS EN IEC 63000 :2018
- The Ecodesign for Energy-Related Products and Energy Information (Amendment) (EU Exit) Regulations 2019
 - BS EN 50563: 2011+A1: 2013

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