EU & UK Declaration of Conformity



We, the responsible manufacturer;

Company Name: Mascot Electronics AS

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Visiting Address: Mosseveien 109, N-1624 Gressvik, NORWAY

Telephone: (+47) 69 36 43 00 E-mail: sales@mascot.com WEB: www.mascot.com

declare that this Declaration is issued under our sole responsibility and belongs to the following product(s):

Product and Power Supply Unit

intended purpose:

Brand(s): and/or (may also carry additional customer name, logo or trade mark)

Type(s)/Model(s)/

UDI-DI: Type name may be followed by:

3825

"" denoting 2 MOOP protection
"P" denoting 2 MOPP protection

"B" denoting 2 MOOP protection, "open frame" for building-in (= PCB only)
"BP" denoting 2 MOPP protection, "open frame" for building-in (= PCB only)

may also carry additional customer model name or part number

Batch / Serial No./

UDI-PI:

all CE- and/or UKCA- marked products produced from the date indicated below

(for production date: see marking on the product)

Description: Input: max. 0.25 A, 100-240 VAC 50-60 Hz, Class II

Output: 5 V version: 4.5 - 5.5 VDC*, max. 1.0 A, max. 5.5 W

6 V version: 5.51 - 6.5 VDC*, max. 1.0 A, max. 6.5 W 7.5 V version: 6.51 - 8.0 VDC*, max. 1.0 A, max. 7.2 W 9 V version: 8.01 - 10.0 VDC*, max. 0.9 A, max. 7.2 W 12 V version: 10.01 - 12.5 VDC*, max. 0.72 A, max. 7.2 W

* = a fixed value within the range

The product(s) described above are in conformity with the relevant European Union harmonisation legislation for CE-marking:

93/42/EEC	EU Directive - General Medical Devices (MDD), Risk Class I Device will from 26.05.2021 be repealed by "MDR" Regulation (EU) 2017/745
Regulation (EU) 2017/745	EU Medical Devices Regulation (MDR), Risk Class I Device will from 26.05.2021 repeal "MDD" Directive
2014/30/EU	EU Directive - Electromagnetic Compatibility (EMC) recast, repealing Directives 2004/108/EC & 89/336/EEC
2009/125/EC	EU Directive - Energy Related Products, Ecodesign (ERP) recast, repealing Directive 2005/32/EC (EUP)
2015/863/EU	EU Directive - Restriction on use of Hazardous Substances in EEE ("RoHS3") recast, repealing Directives 2002/95/EC, 2008/35/EC & 2011/65/EU

The product(s) described above are in conformity with the relevant U.K. legislation for UKCA-marking:

Electrical Equipment (Safety) Regulations 2016

Electromagnetic Compatibility (EMC) Regulations 2016

The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020, Risk Class I Device

Ecodesign for Energy-Related Products (External Power Supplies) Regulations 2020

Draft Regulation, awaiting implementation

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012

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The following harmonised standards and technical specifications have been applied:

(International editions and comments indicated in brackets):

Electrical Safety (to MDR/MDD-Directives):

EN 60601-1:2006 + /AC:2010 +/A1:2013 Medical electrical equipment, Edition 3.1 EN 60601-1

(IEC 60601-1:2005 + /A1:2012) (also IEC 60601-1:2005 Amd.2:2020, but not yet harmonized as EN-norm)

Electromagnetic Compatibility (to MDR/MDD-Directives):

EN 60601-1-2:2015 Medical equipment, EMC - Requirements and tests, Edition 4.0 EN 60601-1-2

(IEC 60601-1-2:2014, Edition 4.0)

Electromagnetic Compatibility (to EMC-Directive):

EN 61000-6-1:2007 Immunity-residential, comm. & light-industrial environment, Edition 2.0 EN 61000-6-1

(IEC 61000-6-1:2005, Edition 2.0) (also IEC 61000-6-1:2016, Edition 3.0, not yet an EN-norm)

EN 61000-6-3:2007 + /A1:2011 & /AC:2012 Emission-residential, comm. & light-industrial environment, Edition 2.1 EN 61000-6-3

(IEC 61000-6-3:2007 + /A1:2010)

Ecodesign to EU ERP-Directive:

implementing Directive 2005/32/EC with regard to ecodesign requirements for no-Commission Regulation (EC) No 2019/1782

load condition electric power consumption and average active efficiency of external power supplies (Repealing Commission Regulation (EC) No 2009/278)

Ecodesign for U.K.:

Draft "Ecodesign for Energy-Related Products (External Power Supplies) Regulations Draft Regulation only (awaiting implementation)

Ecodesign for U.S.A. (Note: depends on battery used !):

10 CFR Part 430 - Energy Conservation Program for Consumer Products, **US Code of Federal Regulations (CFR)**

10 CFR Part 430, Subpart B - Test Procedures Also called "DoE compliance"

10 CFR Appendix Y to Subpart B of Part 430, Uniform Test Method for Measuring the Energy Consumption of Battery Chargers or 10 CFR Appendix Z to Subpart B of Part 430, Uniform Test Method for Measuring the Energy Consumption of External

Power Supplies, whichever applicable.

California Code of Regulations (CCR) CCR Title 20 - Public Utilities and Energy,

Also called "CEC-400 compliance" referring to CEC-400-2017-

Division 2 - State Energy Resources Conservation and Development Commission, 002 "2016 Appliance Efficiency Regulations" issued by Chapter 4 - Energy Conservation, Article 4 - Appliance Efficiency Regulations,

Sections 1601 to 1609

Restriction of the Use of certain Hazardous Substances (RoHS) for EU:

EU Directive - Restriction on use of Hazardous Substances in EEE Restriction of the 2015/863/EU "RoHS3"

Use of certain Hazardous Substances in Electrical and Electronic Equipment

Restriction of the Use of certain Hazardous Substances for UK:

The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

Regulations 2012

Additional Information:

California Energy Commission

Compliance with harmonised standards and technical specifications may have been verified by the manufacturer, by third party testing or by a Certification Body (NCB).

The products are considered Risk Class I devices according to EU Medical Devices Directive, EU Medical Devices Regulation and the U.K. Medical Devices (Amendment etc.) (EU Exit) Regulations 2020.

The product(s) may be produced at production sites (for specific product: see "Made in"-marking on the product):

- Mascot Baltic OÜ, Taevakivi 15, EE-13619 Tallinn, ESTONIA

Mascot Power Supplies (Ningbo) Co., Ltd, No.128 Jinchuan Road, Zhenhai, Ningbo 315221, CHINA

The production sites are certified to standard EN 29001:2015 (ISO 9001:2015) by:

- Mascot Baltic OÜ: Metrosert, certificate ref. K-144

- Mascot Power Supplies (Ningbo) Co.,Ltd: DNV-GL, certificate ref. 179027-2015

Signed on behalf of Mascot Electronics AS

Fredrikstad, Norway 2021-04-09

Finn-Erik Wallin, Compliance ivlanager

Place of issue Date of issue Name, function, signature