# EU & UK Declaration of Conformity



### We, the responsible manufacturer;

we, the responsible manufacturer,				
Company Name:	Mascot Electronics AS			
Postal Address:	P.O.Box 177, N-1601 Fredrikstad, NORWAY			
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 maile (may also carry additional customer name, logo or trade mark)			
Type(s)/Model(s)/	3520			
UDI-DI:	(may also carry additional customer model name or part number)			
Batch / Serial No./	all CE- and/or UKCA- marked products produced from the date indicated below			
UDI-PI:	(for production date: see marking on the product)			
Description:	Input: max. 2.4 A, 220 - 240 VAC, 50 Hz			
	Output: 4 - 60 VDC, max. 17A cont., max. 20 A intermittent, max. 294 W			
	or			
	Input: max. 4.3 A, 110 - 120 VAC, 60 Hz			
	Output: 4 - 60 VDC, max. 17A cont., max. 20 A intermittent, max. 252 W			

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

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2014/35/EU	EU Directive - Safety of electrical equipment ("Low-Voltage Directive") (LVD) recast, repealing Directives 2006/95/EC & 73/23/EEC	
2014/30/EU	EU Directive - Electromagnetic Compatibility (EMC) recast, repealing Directives 2004/108/EC & 89/336/EEC	
93/42/EEC	EU Directive - General Medical Devices (MDD), Risk Class I Device will from 26.05.2021 be repealed by "MDR" Regulation (EU) 2017/745	
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

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	EN 60601-1:2006 + /AC:2010 +/A1:2013 (IEC 60601-1:2005 + /A1:2012)	Medical electrical equipment, Edition 3.1
EN 60601-1-11	EN 60601-1-11:2010 Medical electrical equipment and systems used in the home healthcare environment, Edition 1.0 (IEC 60601-1-11:2010 +/COR1:2011, Ed.1.0) (also IEC 60601-1-11:2015 +/A1:2020, Ed.2.1, but not yet an EN-norm) NOTE: for products rated IPx1 or higher to standard EN 60529 only	

Electromagnetic Compatibility (to MDR/MDD-Directives):

EN 60601-1-2	EN 60601-1-2:2015	Medical equipment, EMC - Requirements and tests, Edition 4.0
	(IEC 60601-1-2:2014, Edition 4.0)	

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Electromagnetic Com	patibility (to EMC-Direct	īve):				
EN 61000-6-1	EN 61000-6-1:2007 (IEC 61000-6-1:2005, Edition 2.0)	Immunity-residential, comm. & light-industrial environment, Edition 2.0 (also IEC 61000-6-1:2016, Edition 3.0, not yet an EN-norm)				
EN 61000-6-3	EN 61000-6-3:2007 + /A1:2011 8 (IEC 61000-6-3:2007 + /A1:2010)	· · · ·				
Ecodesign to EU ERP-I	Ecodesign to EU ERP-Directive:					
Commission Regulation (EC) No 2019/1782		implementing Directive 2005/32/EC with regard to ecodesign requirements for no- load condition electric power consumption and average active efficiency of external power supplies (Repealing Commission Regulation (EC) No 2019/1782 from 2020- 04-01) ( <i>Note: not applicable to Battery Chargers, ref. Article 1.2 item c</i> ) )				
Ecodesign for U.K.:						
Draft Regulation only	(awaiting implementation)	Draft "Ecodesign for Energy-Related Products (External Power Supplies) Regulations 2020" (Note: not applicable to Battery Chargers)				
Ecodesign for U.S.A. (Note: depends on battery used !):						
US Code of Federal Re Also called "DoE compliance"	•	10 CFR Part 430 - Energy Conservation Program for Consumer Products, 10 CFR Part 430, Subpart B - Test Procedures, 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) Also called "CEC-400 compliance" referring to CEC-400-2017- 002 "2016 Appliance Efficiency Regulations" issued by California Energy Commission		CCR Title 20 - Public Utilities and Energy, Division 2 - State Energy Resources Conservation and Development Commission, Chapter 4 - Energy Conservation, Article 4 - Appliance Efficiency Regulations, Sections 1601 to 1609				
Restriction of the Use of certain Hazardous Substances (RoHS) for EU:						
2015/863/EU "RoHS3	n	EU Directive - Restriction on use of Hazardous Substances in EEE Restriction of the 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 Informatio						

### Electromagnetic Compatibility (to EMC-Directive):

Additional Information:

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.

Metrosert, certificate ref. K-144

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:

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

The most recent issue of this Declaration is available at www.mascot.com.

Fredrikstad, Norway

2021-03-02

Place of issue

Date of issue

Signed on behalf of Mascot Electronics AS

Finn-Erik Wallin, Compliance Manager Name, function, signature

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