EU & UK Declaration of Conformity



We, the responsible manufacturer;

Company Name:	Mascot Electronics AS				
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declare that this Declaration is issued under our sole responsibility and belongs to the following product(s): Product and Deskton Power Supply

Product and intended purpose:	Desktop Power Supply				
Brand(s):	and/or massion (may also carry additional customer name, logo or trade mark)				
Type(s)/Model(s)/ UDI-DI:	3220 (may also carry additional customer model name) (model 3220 apply 2MOOP protection to IEC 60601-1, model 3220P apply 2MOPP)				
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.2.1A 100-120V/220-240VAC 50-60Hz, Class I or II				
	Output: 5V-version: 4 - 6VDC max. 8.5A/51W				
	9V-version: 6 - 9VDC max. 8.5A/77W				
	12V-version: 9 - 13.2VDC max. 8.5A/103W				
	16V-version: 12 - 16.8VDC max. 7.7A/102W				
	24V-version: 16.8 - 24VDC max. 6.0A/101W				
	28V-version: 24 - 28VDC max. 4.4A/106W				
	36V-version: 28 - 38VDC max. 3.6A/103W				
	48V-version: 38 - 48VDC max. 2.7A/103W				
	60V-version: 48 - 63VDC max. 2.1A/101W				
	64V-version: 63 - 67VDC max. 1.6A/100W				
	NOTE: For compliance with standard EN 60601-1 output terminals >60VDC must be inaccessible to the operator.				

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

(EU) 2017/745	EU Regulation - Medical Devices Regulation (MDR), Risk Class I Device			
	amending Directive 2001/83/EC, Regulations (EC) 178/2002 & (EC) 1223/2009 and			
	repealing Directives 90/385/EEC & 93/42/EEC			
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: The Medical Devices (Amendment etc.) (EU Exit) Regulations 2020, Risk Class I Device

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):

EN 60601-1	EN 60601-1:2006 + /AC:2010 +/A1:2013 (IEC 60601-1:2005 + /A1:2012)	Medical electrical equipment, Edition 3.1			
Electromagnetic Compatibility (to MDR):					
EN 60601-1-2	EN 60601-1-2:2015 (IEC 60601-1-2:2014, Edition 4.0)	Medical equipment, EMC - Requirements and tests, Edition 4.0			
Restriction of the Use of certain Hazardous Substances (RoHS) for EU:					

2015/863/EU "RoHS3"

EU Directive - Restriction on use of Hazardous Substances in EEE Restriction of the Use of certain Hazardous Substances in Electrical and Electronic Equipment

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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:

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 Device Regulation (MDR) 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, certified to standard EN 29001:2015 (ISO 9001:2015) by Metrosert, certificate ref. K-144
- Mascot Power Supplies (Ningbo) Co.,Ltd, No.128 Jinchuan Road, Zhenhai, Ningbo 315221, CHINA, certified to standard EN 29001:2015 (ISO 9001:2015) by DNV-GL, certificate ref. 179027-2015

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

Fredrikstad, Norway

2021-08-25

Place of issue

Date of issue

Signed on behalf of Mascot Electronics AS

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