

# EU Declaration of Conformity



## 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:	DeskTop Power Supply Unit (also for use with Medical Equipment)		
Brand(s):	and/or <b>MASCOT</b> (may also carry customer name, logo, trade mark and/or part number)		
Type(s)/Model(s):	2020, 2021 and 2022		
Description:	Input: 1.2A 100-240VAC 50-60Hz Cl.I (type 2020) / Cl.II (types 2021 & 2022)		
	Output: 9V-version:	7.5 - 12VDC	max. 4.5A/40W
	12V-version:	12 - 15VDC	max. 4.5A/60W
	16V-version:	15 - 20VDC	max. 3.75A/60W
	24V-version:	20 - 30VDC	max. 2.5A/60W

The products are in conformity with the relevant European Union harmonisation legislation:

93/42/EEC	EU Directive - General Medical Devices (MDD), Risk Class I Device <i>will from 05.05.2020 be repealed by Regulation (EU) 2017/745</i>
2015/863/EU	EU Directive - Restriction on use of Hazardous Substances in EEE ("RoHS3") <i>recast, repealing Directives 2002/95/EC, 2008/35/EC &amp; 2011/65/EU</i>

The following harmonised standards and technical specifications have been applied:

### Electrical Safety (to MDD-Directive):

EN 60601-1	EN 60601-1:2006 + /AC:2010 +/A1:2013 (IEC 60601-1:2005 + /A1:2012)	Medical electrical equipment, Edition 3.1
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### Electromagnetic Compatibility (to MDD-Directive):

EN 60601-1-2	EN 60601-1-2:2007 (IEC 60601-1-2:2007)	Medical equipment, EMC - Requirements and tests, Edition 3.0
	from 31/12/2018: EN 60601-1-2:2015 (IEC 60601-1-2:2014)	Medical equipment, EMC - Requirements and tests, Edition 4.0

### 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 the General Medical Devices Directive.

The products are produced at production site: Mascot Baltic OÜ, Taevakivi 15, EE-13619 Tallinn, ESTONIA.

The production site is certified to standard EN 29001:2015 (ISO 9001:2015) by: Metrosert, ref. K-144.

Fredrikstad, Norway	2019-05-22	Signed on behalf of Mascot Electronics AS  Finn-Erik Waalin, Compliance Manager
Place of issue	Date of issue	Name, function, signature