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 and Power Supply Unit

intended purpose:

e:

and/or must be and/or may also carry additional customer name, logo or trade mark)

Type(s)/Model(s)/

2124 & 2125

UDI-DI:

Brand(s):

(may also carry additional customer model name or part number)

Batch / Serial No./ UDI-PI: all CE-marked products produced from the date indicated below

(for production date: see marking on the product)

Description: Input: 0.35A 100 - 240VAC 50-60 Hz, Cl. II

Output: 6V-version: 4.5 - 7.5VDC max. 1.5A/9W

9V-version: 7.5 - 11VDC max. 1.5A/13.5W 12V-version: 11 - 15VDC max. 1.25A/15W 16V-version: 15 - 18VDC max. 1.0A/16W 24V-version: 20 - 30VDC max. 650mA/16W 48V-version: 40 - 52VDC max. 330mA/16W

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

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 | Device
will from 05.05.2020 be repealed by Regulation (EU) 2017/745

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 following harmonised standards and technical specifications have been applied:

(International editions and comments indicated in brackets)

Electrical Safety (to LVD- & MDD-Directives):

EN 60950-1 EN 60950-1:2006 + /A1:2010, + /A11:2009, + /AC:2011, + /A12:2011 + /A2:2013 IT-equipment (ITE), Edition 2.2

(IEC 60950-1:2005 modified + /A1:2009 modified + /A2:2013 modified, Edition 2.2)

(will from 20.06.2019 be replaced by standard EN 62368-1:2014 + /AC:2015, Edition 2.0 A/V, ITE & COMM. Equipm.)

(IEC 62368-1:2014, Edition 2.0)

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

(IEC 60601-1:2005 + /A1:2012)

Electromagnetic Compatibility (to EMC- & MDD-Directives):

EN 61000-6-1	EN 61000-6-1:2007 (IEC 61000-6-1:2005, Edition 2.0) (<i>also IEC 61</i>	Immunity-residential, comm. & light-industrial environment, Edition 2.0 000-6-1:2016, Edition 3.0, not yet an EN-norm)
EN 61000-6-3	EN 61000-6-3:2007 + /A1:2011 & /AC:2012 (IEC 61000-6-3:2007 + /A1:2010)	Emission-residential, comm. & light-industrial environment, Edition 2.1
EN 55022	EN 55022:2010 + /AC:2011 Emission-IT-Equipment, Edition 6.0 (CISPR 22:2008 modified, Edition 6.0)(Note: CISPR 22 is now replaced by CISPR 32:2012)	
EN 55024	EN 55024:2010 (CISPR 24:2010, Edition 2.0) (also CISPR 24:20	Immunity-IT-Equipment, Edition 2.0 010 + /Corr.1:2011 + /A1:2015, Edition 2.1, but not yet an EN-norm)
EN 55032	EN 55032:2012 + /AC:2013 (CISPR 32:2012 + /Corr.1:2012 + /Corr.2:2012	Emission-Multimedia Equipment, Edition 1.0

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

Medical equipment, EMC - Requirements and tests, Edition 4.0

(IEC 60601-1-2:2007 modified, Edition 3.0)(Note: for IEC: Edition 3.0 is replaced by IEC 60601-1-2:2014, 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).

Type 2124 is for Direct Plug-In (when used with exchangeable mains plug-adapters) and for detachable mains cord. Type 2125 may be delivered with 2-pins IEC 60320 inlet for detachable mains cord or with non-detachable mains cord) and may also be delivered as protected against ingress of objects and water according to IP67 to standard EN/IEC 60529 (fitted with non-detachable mains cord and filled with PUR compound)

The products are considered Risk Class I devices according to the General Medical Devices Directive.

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

Mascot Electronics AS Mascot Baltic OÜ Mascot Power Supplies (Ningbo) Co.,Ltd

Taevakivi 15 No.128 Jinchuan Road, Zhenhai P.O.Box 177.

N-1601 Fredrikstad, EE-13619 Tallinn Ningbo 315221

NORWAY ESTONIA CHINA

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

Mascot Electronics AS: Mascot Baltic OÜ: Mascot Power Supplies (Ningbo) Co.,Ltd:

Kiwa Teknologisk Institutt Metrosert

certificate ref. 044 certificate ref. K-144 certificate ref. 179027-2015

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

Signed on behalf of Mascot Electronics AS

Finn-Erik Wailin, Compliance i lanager

Fredrikstad, Norway 2018-01-29

Place of issue Date of issue Name, function, signature