

EU 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 intended purpose: **Power Supply Unit**

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

Type(s)/Model(s)/ UDI-DI: **3820-series**
(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: max. 1,6 A 100-240 VAC 50-60 Hz, Class I or II**
Output: type 3820-12: 12.0-14.9 VDC (fixed within the range), max. 8.33 A
type 3820-18: 15.0-20.9 VDC (fixed within the range), max. 8 A
type 3820-24: 21.0-26.9 VDC (fixed within the range), max. 5.71 A
type 3820-30: 27.0-32.9 VDC (fixed within the range), max. 4.44 A
type 3820-36: 33.0-38.9 VDC (fixed within the range), max. 3.63 A
type 3820-42: 39.0-44.9 VDC (fixed within the range), max. 3.07 A
type 3820-36: 45.0-50.0 VDC (fixed within the range), max. 2.66 A

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

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will from 26.05.2021 be repealed by "MDR" Regulation (EU) 2017/745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 following harmonised standards and technical specifications have been applied:

(International editions and comments indicated in brackets):

Electrical Safety and Electromagnetic Compatibility to MDR/MDD-Directives:

EN 60601-1 EN 60601-1:2006 + /AC:2010 +/A1:2013 Medical electrical equipment, Edition 3.1
(IEC 60601-1:2005 + /A1:2012)

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)

Ecodesign (to 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) (Note: not applicable to Medical Devices, ref. Article 1.2)

Ecodesign for U.S.A.:

US Code of Federal Regulations (CFR)
Also called "DoE compliance" 10 CFR Part 430 - Energy Conservation Program for Consumer Products,

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

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.

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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

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

Signed on behalf of Mascot Electronics AS

Fredrikstad, Norway

Place of issue

2020-06-29

Date of issue

A handwritten signature in blue ink that reads 'Finn-Erik Wailin'.

Finn-Erik Wailin, Compliance Manager

Name, function, signature