


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 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: **3823-XX (for explanation of "xx", see Description below)
(may also carry additional customer model name or part number)**
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. 0.4 A, 100-240 VAC 50-60 Hz, Class II
Output: 3823-50: 5.0 - 5.9 VDC max. 2.4 A
3823-60: 6.0 - 7.0 VDC max. 2.0 A
3823-75: 7.1 - 9.0 VDC max. 1.71 A
3823-90: 9.0 - 10.0 VDC max. 1.33 A
3823-12: 10.0 - 14.9 VDC max. 1.6 A
3823-15: 15.0 - 16.9 VDC max. 1.07 A
3823-18: 17.0 - 19.9 VDC max. 0.94 A
3823-24: 20.0 - 29.9 VDC max. 0.8 A**

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

93/42/EEC	EU Directive - General Medical Devices (MDD), Risk Class I Device <i>will from 26.05.2021 be repealed by "MDR" Regulation (EU) 2017/745</i>
Regulation (EU) 2017/745	EU Medical Devices Regulation (MDR), Risk Class I Device <i>will from 26.05.2021 repeal "MDD" Directive</i>
2014/30/EU	EU Directive - Electromagnetic Compatibility (EMC) <i>recast, repealing Directives 2004/108/EC & 89/336/EEC</i>
2009/125/EC	EU Directive - Energy Related Products, Ecodesign (ERP) <i>recast, repealing Directive 2005/32/EC (EUP)</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 & 2011/65/EU</i>

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

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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 Medical electrical equipment, Edition 3.1
(IEC 60601-1:2005 + /A1:2012) (also IEC 60601-1:2005 Amd.2:2020, but not yet harmonized as EN-norm)

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)

Electromagnetic Compatibility (to EMC-Directive):

EN 61000-6-1 EN 61000-6-1:2007 Immunity-residential, comm. & light-industrial environment, Edition 2.0
(IEC 61000-6-1:2005, 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 & /AC:2012 Emission-residential, comm. & light-industrial environment, Edition 2.1
(IEC 61000-6-3:2007 + /A1:2010)

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 2009/278)

Ecodesign for U.K.:

Draft Regulation only (awaiting implementation) Draft "Ecodesign for Energy-Related Products (External Power Supplies) Regulations 2020"

Ecodesign for U.S.A. (Note: depends on battery used !):

US Code of Federal Regulations (CFR) 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.
Also called "DoE compliance"

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" 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 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.

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

Signed on behalf of Mascot Electronics AS

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

Fredrikstad, Norway

Place of issue

2021-04-09

Date of issue