EU & UK 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 intended purpose:	**Power Supply Unit**
Brand(s):	**and/or** (may also carry additional customer name, logo or trade mark)
Type(s)/ Model(s)/UDI-DI:	**3320** (may also carry additional customer model name) **models: 3320-50, 3320-60, 3320-75, 3320-90, 3320-12, 3320-15, 3320-18, 3320-24 & 3320-36**
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. 1.35 A 100-120 V / 220-240 VAC 50-60 Hz, Class I or II** **Output: 3320-50: 5 VDC ± 3% max. 8 A / 40 W** **3320-60: 6 VDC ± 3% max. 6.66 A / 40 W** **3320-75: 7.5 VDC ± 3% max. 7 A / 40 W** **3320-90: 9 VDC ± 3% max. 6 A / 40 W** **3320-12: 12 VDC ± 3% max. 5 A / 40 W** **3320-15: 15 VDC ± 3% max. 4 A / 40 W** **3320-18: 18 VDC ± 3% max. 3.33 A / 40 W** **3320-24: 24 VDC ± 3% max. 2.5 A / 40 W** **3320-36: 36 VDC ± 3% max. 1.66 A / 40 W**

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

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**
(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**
2009/125/EC **)*	**EU Directive - Energy Related Products, Ecodesign (ERP)** **recast, repealing Directive 2005/32/EC (EUP)**
2015/863/EU **Also 2011/65/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:

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 LVD-Directive):

EN 62368-1 **)*	**EN 62368-1:2014 + /AC:2015 + /AC:2017 + /A11:2017** **(IEC 62368-1:2014 + /COR1:2015 + /COR2:2015, Edition 2.0) (also *IEC 62368-1:2018 +/COR1:2020, Ed 3.0, not yet an EN-norm)***	**A/V, IT & Comm., Edition 2.0**

Electrical Safety and Electromagnetic Compatibility (to MDR-Regulation):

EN 60601-1	**EN 60601-1:2006 + AC:2010 +A1:2013 + AC:2014 + A12:2014 + A2:2021** **(IEC 60601-1:2005 + /A1:2012+ /A2:2020**	**Medical electrical equipment, Ed 3.2**
EN 60601-1-2	**EN 60601-1-2:2015 + A1:2021** **(IEC 60601-1-2:2014 +A1:2020, Edition 4.1)**	**Medical equipment, EMC - Requirements and tests, Edition 4.1**

Electromagnetic Compatibility (to EMC-Directive):

EN 61000-6-1 **)*	**EN 61000-6-1:2019** **IEC 61000-6-1:2016, Edition 3.0**	**Immunity-residential, comm. & light-industrial environment, Edition 3.0**
EN 61000-6-3 **)*	**EN 61000-6-3:2021** **(IEC 61000-6-3:2020)**	**Emission-residential, comm. & light-industrial environment, Edition 3.0**
EN 55032 **)*	**EN 55032:2015 + AC:2016 + A11:2020 + A1:2020** **CISPR 32:2015 + A1:2019**	**Emission-Multimedia Equipment, Edition 1.0**
EN 55025 **)*	**EN 55035:2017** **(CISPR 35:2016, Edition 1.0)**	**Immunity- Multimedia Equipment, Edition 1.0**

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 2019/1782 from 2020-04-01) (*Note: not applicable to Battery Chargers, ref. Article 1.2 item c*))**

Ecodesign for U.K.:

Draft Regulation only (awaiting implementation) **)*	**Draft "Ecodesign for Energy-Related Products (External Power Supplies) Regulations 2020" (*Note: not applicable to Battery Chargers*)**

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,** **10 CFR Part 430, Subpart B - Test Procedures,** **10 CFR Appendix Z to Subpart B of Part 430, Uniform Test Method for Measuring the Energy Consumption of External Power Supplies.**
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).

**) used above denotes verified by the manufacturer only.*

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 products provides two Means Of Patient Protection (2 MOPP) to standard IEC 60601-1.

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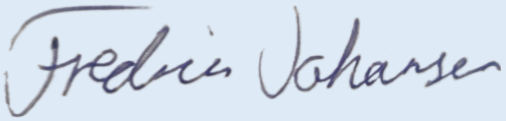
The product(s) may be produced at production sites (for specific product: see "Made in"-marking on the product)**:**

- **Mascot Baltic OÜ, Taevakivi 15, EE-13619 Tallinn, ESTONIA, 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.

Signed on behalf of Mascot Electronics AS

Fredrikstad, Norway	**2024-09-23**	 **Fredrik Johansen, Compliance Manager**
Place of issue	Date of issue	Name, function, signature