

EGSTON System Electronics Eggenburg GmbH

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EU Declaration of Conformity

Eggenburg, 14.09.2021

Product Family:

Egston Power Supply

Type:

N1hxSW3 30

This type is a family of switched mode power supplies.

Where "x" can be

F (Cable module), P (PCB module), K (Terminal module), I (Insulated cable module) and denoting cable connection version

This declaration is valid only for output voltage types with 12V and also for 24V types.

In case of medical use: The power supplies are intended to be integrated into a device or included as an accessory by a medical product manufacturer.

The family is compliant to the following European regulations:

- Low Voltage Directive 2014/35/EU
- EMC Directive 2014/30/EU
- EUP Directive 2009/125/EC with Commission Regulation (EU) 2019/1782
- ROHS Directive 2011/65/EU

Products are not medical devices but they fulfil some of the essential requirements of Medical Device Regulation (EU) 2017/745 and following harmonised standards:

- EN 62368-1:2014
- EN 55032:2015+A11:2020
- EN 55035:2017+A11:2020
- EN 60601-1:2006+A1:2013
- EN 60601-1-2:2015
- EN 60335-1:2012 + A11:2014 + A13:2017 + A1:2019 + A14:2019 + A2:2019
- EN 61558-2-16:2009 + A1:2013
- EN 55014-1:2017 + A11:2020
- EN 55014-2:1997 + A1:2001 + A2:2008
- EN 61347-2-13:2014
- EN 61347-1:2015

First application of the CE mark was 2017. The quality of the product is ensured by a certified quality management system according to ISO 9001.

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Mag. Frank Wolfinger

General Management Firmenbuch: FN 282750i, Lar

ndesgericht Krems/Donau, UID/VAT ATUG2811014, DVR 3001343 UR-Acc: 528 530 011/52, Bank Code: 12000, BIC: BKAUATWW, IBAN: AT66 1200 0528 5300 1152 UniCredit Bank Austria AG, UniCredit Bank Austria AG, USD-Acc: 343 138 286/04, Bank Code: 12000, BIC: BKAUATWW, IBAN: AT67 1200 0343 1382 8604