

EU Declaration of Conformity

Eggenburg, 27.09.2021

Product Family: Power Supply

Type: E2OFxW3 150

This type is a family of built in switched mode power supplies.

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 +Delegated Directive (EU) 2015/863 +Delegated Directive (EU) 2018/736

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 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

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