

UK 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 UK regulations:

- Electrical Equipment (Safety) Regulations 2016
- Electromagnetic Compatibility Regulations 2016
- The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012
- The Ecodesign for Energy-Related Products and Energy Information (Amendment) (EU Exit) Regulations 2019 with Commission Regulation (EU) 2019/1782

Products are not medical devices but they fulfil some of the essential requirements of Medical Devices Regulations 2002 and following harmonised standards:

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

First application of the UKCA mark was 2021. 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