

# **EU Declaration of Conformity**

We, the FRIWO Gerätebau GmbH, hereby confirm, that the product:

Type: FW8002M/xx; FW8002M/EU/xx; FW8002MUSB/05; FW8002MUSB/EU/05; FW8002.1M/xx; FW8002.1M/EU/xx; FW8002.1MUSB/05; FW8002.1MUSB/EU/05; NE0006.0-I-X-xx.

, where "xx" denotes the output voltage, 5-24V.

#### Additional information:

with the enclosed description fulfils the requirements of,

## Low Voltage Directive (LVD) 2014/35/EU

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of electrical equipment designed for use within certain voltage limits.

### Electromagnetic compatibility (EMC) 2014/30/EU

Directive of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.

**Restriction of Hazardous Substances (RoHS) Directive 2011/65/EU** on the restriction of the use of certain hazardous substances with the harmonized norm EN IEC 63000:2018, including the delegated Directive EU 2015/863 (RoHS 3) the modification of Annex II to Directive 2011/65 / EU

**Energy-Related Products (ErP)** Ecodesign requirements for external power supplies pursuant to Directive 2009/125/EC. The Ecodesign for Energy-Related Products and Energy Information (Amendment)(EU Exit) Regulations 2019

The following standards were used to assess the equipment:

**LVD:** EN 62368-1:2014+A11:2017,

EN 60601-1:2006 + A1:2013 + A12:2014 + A2:2021

**EMC:** EN 55032:2015/A11:2020, EN 55035:2017/A11:2020,

EN 60601-1-2:2015 + A1:2021

**RoHS:** EN IEC 63000:2018

**ErP:** Commission Regulation (EU) 2019/1782

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ppa. Dominik Wöffen Chief Operation Officer i.A. Andreas Frehland Head of Laboratory and Approbation

### Additional information:

The safety requirements of the medical device standard EN 60601-1 and HB standard EN 62368-1:2014+A11:2017 are stricter than the safety requirements of typical harmonized standards for the Directive 2014/35/EU (LVD). Therefore, the safety objectives of the Directive 2014/35/EU are considered to be fulfilled.

#### FRIWO Gerätebau GmbH