

# EC Declaration of Conformity for medical devices

(as defined by directive for medical devices 93/42/EEC, MDD 2007, Annex VII)



## DeMeTec GmbH

Lützelwiesen 5, 35428 Langgöns (Germany)

We hereby declare, that the product

### **Isolated Power Supply – IPs Version 3.2**

Type: IPs-330R3-2S, IPs-330R3-4K, IPs-330R3-8K, IPs-630R3-2S,  
IPs-630R3-8K, IPs-1000R3-2S, IPs-1000R3-8K-120V,  
IPs-1000R3-8K, IPs-1400R3-2S, IPs-1400R3-8K

was manufactured in harmony with the technical documentation as defined by Annex VII, section 3 of the medical device directive and that it corresponds to the requirements of the following directive:

### **Medical Device Directive 93/42/EEC**

Meeting the following standards: **EN 60601-1:2006/AC:2010/A1:2013**  
**EN 60601-1-2:2007/AC:2010**

As well the following guideline will be followed:

### **Directive 2011/65/EU (RoHS-II)**

In compliance with the national Electrical and Electronic Equipment fabric Regulation



Langgöns, 2018-03-12

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**Manager**  
**Head of Development Department**

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**Quality Management Officer**  
**Regulatory Affairs**