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EC-Conformity Declaration



For the following equipment:

Product Name Open Frame Medical Power Supply

Model Designation GTMG3074P-05VV-X.X-FW

Manufacturer Name

Manufacturer Address

- | | |
|------------------------------|--|
| 1. GlobTek, Inc. USA | GlobTek, Inc. USA, 186 Veterans Drive, Northvale, NJ USA 07647 |
| 2. GlobTek (Suzhou) Co. Ltd. | GlobTek (Suzhou) Co. Ltd., Building 4, City Illumination Industrial Park, 76 East Jinling Road, Weting Town, Suzhou Industrial Park, Suzhou, 215021China |
| 3. GlobTek Deutschland GmbH | GlobTek Deutschland GmbH, Hafenweg 26a, 48155 Münster, Germany |

is herewith confirmed to comply with the requirements set out in the Council Directive on the Approximation of the Laws of the Member States relating to Electromagnetic Compatibility Directive (2014/30/EU) (formerly 2004/108/EC), Low-Voltage Directive (2014/35/EU) (formerly 2006/95/EC) and the Amendment Directive (93/68/EEC). Eco design Requirements for energy-related products Directive (2009/125/EC) (formerly 2005/32/EC) and conformance to Eup Implementing measure Commission Regulation (278/2009/EC of 26th April 2011 Annex I) RoHS 2 Directive 2011/65/EU

For the evaluation regarding the Directives, the following standards were applied:

- EN 60601-1-2:2013
- EN 61000-3-2:2014
- EN 61000-3-3:2013
- EN 60601-1:2006+A11:2011+A1:2013

- Test Method for Calculating the Energy Efficiency of Single-Voltage External Ac-Dc and Ac-Ac Power Supplies August 11, 2004
- IEEE Std 1515-2000
- IEEE Std 519-2004
- IEC 62301 2011
- IEC 60050
- IEEE 100

The following manufacturer/importer is responsible for this declaration: Company Name: GlobTek, Inc USA

Company Address: 186 Veterans Drive, Northvale, NJ USA 07647

Person responsible for making this declaration:

Name, Surname: Hans Moritz

Position/Title: QA Manager

On Behalf of GlobTek Inc. Signature

Hans Moritz

Northvale, NJ USA April 28th, 2017