

Delivering leading edge, innovative power solutions for over 30 years since 1984

EC Declaration of Conformity



For the following equipment: Modular Medical Power Supply
(Product Name)

tes_)of clone test
(Model Designation)

GlobTek, Inc. USA, 186 Veterans Drive, Northvale, NJ USA 07647
(Manufacturer Name and Address)

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 and applying the following standards:

- MDD (Medical Devices Directive) (93/42/EEC) / Medical Device Regulation (EU) 2017/745
 - Medical Power Supply IEC 60601-1:2005 + A1:2012 (Edition 3.1)+A22020
 - Medical Electrical Equipment for use in the home healthcare environment IEC 60601-1-11:2015+A12020
- Electromagnetic Compatibility Directive (2014/30/EU)
 - EMI (Electro-Magnetic Interference)
 - EN 55032:2015+A11:2020 Class B
 - Harmonized standard of (and equivalent to) EN 55011 and EN 55022
 - Harmonic Flicker EN 61000-3-2:2019
 - Voltage Flicker EN 61000-3-3:2013+A12019
 - EMS (Electro-Magnetic Susceptibility)
 - EN 55035:2017 +A11:2020 or EN55024:2010/A1:2015
 - EN 60601-1-2:2015 (4th Edition)
- RoHS 2.1 / RoHS 3 Directive 2011/65/EU + Amendment (EU) 2015/863
 - EN 50581:2012 (RoHS Standard)
 - BS EN IEC 63000:2018, Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

This declaration is valid for products with date code February 2020 and later. The power supply described above is considered as a component and operated in combination with an end use system. The purchaser of this power supply should conduct system level EMC/EMS testing to verify system level conformance.

The following manufacturer is responsible for this declaration:

GlobTek, Inc USA
186 Veterans Drive, Northvale, NJ USA 07647
(Company Name and Address)

Person responsible for making this declaration:

David Duff
(Name, Surname)

This declaration of conformity is issued under the sole responsibility of the manufacturer

Northvale, NJ USA January 29th, 2020



(Place)

Date

On Behalf of GlobTek Inc. Signature