

DECLARATION OF CONFORMITY

IN ACCORDANCE TO ISO/IEC GUIDE 22

FOR

Activity Monitors

MANUFACTURER: ActiGraph
49 East Chase Street
Pensacola, Florida 32502
Phone: 850-332-7900 Fax: 850-332-7904

MODEL NUMBER: wGT3X-BT, wActiSleep-BT

REPORT #: F2LQ5424A-01E, F2LQ5424A-02E

DIRECTIVES: Medical Devices Directive 93/42/EEC
RTTE Directive (1999/5/EC)

STANDARDS:

- EN 60601-1-2:2007, inc. C:2010 Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- EN 61000-4-2:2009 Electromagnetic Compatibility-Part 4: Testing and Measurement Techniques – Section 2: Electrostatic Discharge Immunity Test
- EN 61000-4-2:2001 Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 2: Electrostatic discharge immunity test
- EN 61000-4-3:2006, inc. A2:2010 Electromagnetic Compatibility-Part 4: Testing and Measurement Techniques – Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
- EN 61000-4-8:2010 Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity test
- EN 55011:2009, inc. A1:2010 Limits and Methods of Measurement of Radio Disturbance, Characteristics of Industrial, Scientific and Medical Radio Frequency Equipment
- EN 55016-2-3:2010 Specification for radio disturbance and immunity measuring apparatus and methods. Methods of measurement of disturbances and immunity. Radiated disturbance measurements.
- EN 55022:2006 Information technology equipment – radio disturbance characteristics – Limits and methods of measurement
- EN 301 489-1 V1.8.1:2008 Electromagnetic Compatibility and Radio Spectrum Matters; Electromagnetic Compatibility standard for radio equipment and services; Part 1: Common technical requirements
- EN 301 489-3 V1.4.1 Electromagnetic Compatibility and Radio Spectrum Matters; Electromagnetic Compatibility Standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices operating on frequencies between 9kHz and 40GHz.

TESTING FACILITIES: F-Squared Laboratories
26501 Ridge Road
Damascus, Maryland 20745

F-Squared Laboratories
16740 Peters Road
Middlefield, Ohio 44062

CKC Laboratories, Inc.
5046 Sierra Pines Drive
Mariposa, CA 9533

The Activity Monitors, wGT3X-BT and wActiSleep-BT, are in effective conformance to the Directives and Standards referenced above.

Authorized by: _____



Date: December 3, 2013

Name: Adam Simon

Title: Quality Manager