

# 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:** GT9X
- REPORT #:** F2LQ6006A-05E, F2LQ6006A-04E, F2LQ6006A-03A
- 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 61000-4-3:2006, inc. A2:2010 Electromagnetic Compatibility-Part 4: Testing and Measurement Techniques – Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test*
  - *EN 61000-4-4:2004, inc. A1:2010 Electromagnetic Compatibility – Part 4: Testing and Measurement Techniques – Section 4: Electrical Fast Transient/Burst Immunity Test*
  - *EN 61000-4-5:2006 Electromagnetic Compatibility – Part 4: Testing and Measurement Techniques – Section 5: Surge Immunity Test*
  - *EN 61000-4-6:2009 Electromagnetic Compatibility – Part 4: Testing and Measurement Techniques – Section 6: Conducted Immunity Test*
  - *EN 61000-4-8:2010 Electromagnetic Compatibility-Part 4: Testing and measurement techniques – Section 8: Power frequency magnetic field immunity test*
  - *EN 55022:2006 inc A1:2007 Information Technology Equipment – Radio Disturbance Characteristics – Limit and Methods of Measurement*
  - *EN 300 489-1 V1.9.2:2011 Electromagnetic Compatibility and Radio Spectrum Matters; EMC standard for radio equipment and services; Part 1: Common technical requirements*
  - *EN 301 489-3 V1.4.1:2002 Electromagnetic Compatibility and Radio Spectrum Matters; EMC standard for radio equipment and services; Part 3 Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 40 GHz*
  - *EN 300 328-2 V1.8.1:2012 Electromagnetic compatibility and Radio Spectrum Matters; Wideband Transmission Systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Part 2: Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive*
  - *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*

**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 95338*

The Activity Monitor, *GT9X*, is in effective conformance to the Directives and Standards referenced above.

Authorized by:



Date: December 3, 2014

Name: Adam T. Simon

Title: Quality/Regulatory Manager