

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:

GT3X+, ActiSleep

REPORT #:

F2LQ4078-01E
F2LQ4078-02S

DIRECTIVES:

Medical Devices Directive 93/42/EEC
Electromagnetic Compatibility Directive 2004/108/EC

STANDARDS:

- Medical Electrical Equipment Part 1: General Requirements for Safety IEC 60601-1:1988+A1:1991+A2:1995
- Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests EN 60601-1-2:2007
- Electromagnetic Compatibility-Part 4: Testing and Measurement Techniques – Section 2: Electrostatic Discharge Immunity Test EN 61000-4-2:1995
- Electromagnetic Compatibility-Part 4: Testing and Measurement Techniques – Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test EN 61000-4-3:1996
- Limits and Methods of Measurement of Radio Disturbance, Characteristics of Industrial, Scientific and Medical Radio Frequency Equipment EN 55011:2007

TESTING FACILITIES:

F-Squared Laboratories
26501 Ridge Road
Damascus, Maryland 20745 USA

F-Squared Laboratories
16740 Peters Road
Middlefield, Ohio 44062 USA

The Activity Monitors, GT3X+ and ActiSleep, are in effective conformance to the Directives and Standards referenced above.

Authorized by:



Date: October 27, 2011

Name:

Adam Simon

Title: Quality Manager