



## Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
ActiGraph	wGT3X-BT

MANUFACTURER		
Name of company	Address	Representative
ActiGraph, LLC	49 East Chase Street Pensacola, Florida 32502 United States of America	Adam Simon Regulatory Affairs Manager

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax EmergoEurope@ul.com

CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class: 1 Self-Certified (active, non-measuring)  Rule: 1 (Annex IX, III. Classification, Page 53) and 12 (Annex IX, III. Classification, Page 55)	-Annex VII of Medical Devices Directive (MDD) 93/42/EEC  -Radio Equipment Directive (RED) 2014/53/EU	-EN 60601-1-2:2007, C:2010 -EN 61000-4-2:2009 -EN 61000-4-2:2001 -EN 61000-4-3:2006 A1:2008 & A2:2010 -EN 61000-4-8:2010 -EN 55011:2009, A1:2010 -EN 55016-2-3:2010 -EN 55022:2006 -EN 55032:2015 -EN 55016-2-3:2010 -EN 300 328-2 v1.9.1:2015 -EN 301 489-1 V2.1.1:2017 -EN 301 489-3 V1.4.1 -EN 301 489-17 V3.2.0:2017



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**ActiGraph, LLC** declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices.

**COMPANY REPRESENTATIVE:** Adam Simon

**TITLE:** Regulatory Affairs Manager

**SIGNATURE:** Adam T. Simon  
Adam T Simon (Nov 20, 2018)

**DATE:** 2018-11-20

