Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

MANUFACTURER		
Name of Company	**Address**	**SRN**
ActiGraph, LLC	49 E. Chase Street Pensacola, Florida 32502 United States of America	Not currently applicable

AUTHORIZED REPRESENTATIVE			
Name of Company	**Address**	**SRN**	**Telephone/fax/email**
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Not currently applicable	+31.70.345.8570 - phone +31.70.346.7299 - fax EmergoEurope@ul.com

PRODUCT IDENTIFICATION		
Product Name	**Product Code / Catalog Number**	**Basic UDI-DI**
ActiGraph	wGT3X-BT	0853048008008UP

Intended Purpose	**Photo**
The ActiGraph activity monitors are small wrist-worn monitors designed for documenting physical movement associated with applications in physiological monitoring. The devices are intended to monitor the activity associated with movement during sleep. The ActiGraph activity monitors can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable.	

RISK CLASS FOR MEDICAL DEVICES	
Device Classification	**Common Specifications**
Class: I, Self-Certified (active, non-measuring) Rule: 12 (Annex IX, III. Classification, Page 55)	-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

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
Intertek	NB 0413	ISO 13485:2016 EN ISO 13485:2016	0085649-01 0098659

ActiGraph declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Device Regulation (MDR) 2017/745
- Radio Equipment Directive (RED) 2014/53/EU

COMPANY REPRESENTATIVE: Adam Simon

TITLE: Regulatory Affairs Manager **SIGNATURE:** Adam T Simon
Adam T Simon (Aug 3, 2020 16:04 CDT)

PLACE: United States of America **DATE:** 2020-08-03

wGT3X-BT Declaration of Conformity (2020-08-03)

Final Audit Report 2020-08-03

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