



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	70 North Baylen Street, Suite 400, Pensacola, FL. 32502 United States of America	US-MF-000007954

AUTHORIZED REPRESENTATIVE

Name of Company	Address	SRN	Telephone/fax/email
Emergo Europe	Westervoortsedijk 60 6827 AT Arnhem The Netherlands	NL-AR-000000116	+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) Rules: 1 & 13 (Annex VIII)	-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



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	-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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NOTIFIED BODY

Name of Company	ID Number	Conformity Assessment Procedure	Certificate Reference(s)
Intertek	NB 0413	ISO 13485:2016 (MDSAP) EN ISO 13485:2016	0085649-02 0108521-01

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

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

COMPANY REPRESENTATIVE: Brian Bell

TITLE: Vice President of Regulatory Affairs

SIGNATURE:

Brian Bell

Brian Bell (Mar 16, 2023 00:00 CDT)

PLACE: Pensacola, FL. United States of America

DATE: European format 16-Mar-2023






wGT3X-BT Declaration of Conformity (2023-03-15)

Final Audit Report

2023-03-16

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