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**
CentrePoint Insight Watch	CPW01	0853048008039V2

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 62479 -EN 60601-1 -EN 60601-1-2:2015 -EN 61000-3-2:2014 -EN 61000-3-3:2013 -EN 61000-4-2:2009

Declaration of Conformity

Compliance Assessment to RoHS Directive	-EN 61000-4-3:2006 A1:2008 & A2:2010 -EN 61000-4-8:2010 -EN 55011:2016+A1:2017 -EN 55016-2-3:2010 -EN 55032:2015 -EN 55016-2-3:2010 -EN 50581:2012 -EN 300 328-2 v2.1.1:2015 -EN 301 489-1 V2.1.1:2017 -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 (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
- Restriction of the use of certain hazardous substances (RoHS) Directive 2011/65/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

CentrePoint Insight Watch Declaration of Conformity (2023-03-15)

Final Audit Report 2023-03-16

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