


# ActiGraph<sup>®</sup>

## Declaration of Conformity

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

| MANUFACTURER     |   |                 |
|------------------|---|-----------------|
| Name of Company  | Address   | SRN             |
| ActiGraph L.L.C. | 70 North Baylen Street,<br>Suite 400,<br>Pensacola, FL. 32502<br>United States of America | US-MF-000007954 |

| AUTHORIZED REPRESENTATIVE |   |                 |  |
|---------------------------|---|-----------------|--|
| Name of Company           | Address   | SRN             | Telephone/fax/email                            |
| Emergo Europe             | Westervoortsedijk 60<br>6827 AT Arnhem<br>The Netherlands | NL-AR-000000116 | +31.70.345.8570 - phone<br>EmergoEurope@ul.com |

| PRODUCT IDENTIFICATION  |  |                 |
|---|--|-----------------|
| Product Name  | Product Code / Catalog Number  | Basic UDI-DI    |
| CentrePoint Insight Watch   | CPW01  | 0853048008039V2 |
| Intended Purpose  | Photo  |                 |
| <p>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.</p> |  |                 |



## Declaration of Conformity

| RISK CLASS FOR MEDICAL DEVICES  |  |
|---|--|
| Device Classification   | Common Specifications  |
| Class: I, Self-Certified (active, non-measuring)<br><br>Rules: 13 (Annex VIII)<br><br>Compliance Assessment to RoHS Directive | -EN 62479<br>-EN 60601-1<br>-EN 60601-1-2:2015<br>-EN 61000-3-2:2014<br>-EN 61000-3-3:2013<br>-EN 61000-4-2:2009<br>-EN 61000-4-3:2006 A1:2008 & A2:2010<br>-EN 61000-4-8:2010<br>-EN 55011:2016+A1:2017<br>-EN 55016-2-3:2010<br>-EN 55032:2015<br>-EN 55016-2-3:2010<br>-EN 50581:2012<br>-EN 300 328-2 v2.1.1:2015<br>-EN 301 489-1 V2.1.1:2017<br>-EN 301 489-17 V3.2.0:2017 |

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:** Thomas Hartshorn

**TITLE:** Head of Quality Assurance & Compliance

**PLACE:** Pensacola, FL, United States of America

**SIGNATURE:**

**DATE:**

22 Mar 2024