Declaration of Conformity

LEAP_Declaration_of_Conformity_07Mar2024

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, 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 LEAP™	LEAP	00853048008053

Intended Purpose	Photo
The ActiGraph LEAP™ is a small, worn activity monitor designed for documenting physical movement associated with applications in physiological monitoring. The device is intended to monitor the activity associated with movement during sleep. The ActiGraph LEAP™ 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 55032: 2015 + A11:2020 + A1:2020 EN 61000-3-3:2013 + A1:2019 + A2:2021 EN IEC 61000-3-2:2019 + A1:2021 EN 55035:2017 + A11:2020 EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4 EN 300 328 V2.2.2 EN 62479:2010 EN IEC 62368-1:2020 + A11:2020

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	IEC 60601-1:2005+A1:2012+A2:2020; EN 60601-1:2006+A1:2013+A2:2021 Basic Safety and Essential Performance IEC 60601-1-2:2014; EN 60601-1-2:2015 EMC IEC 60601-1-6:2010 + A1:2013; EN 60601-1-6:2010+A1:2015 Usability IEC 60601-1-9:2007+A1:2013; EN 60601-1-9:2008+A1:2013 Environmentally Conscious Design IEC 60601-1-11; EN 60601-1-11:2015+A1:2021 Home Healthcare

NOTIFIED BODY			
Name of Company	**ID Number**	**Conformity Assessment Procedure**	**Certificate Reference(s)**
Intertek	NB 0413	ISO 13485:2016 (MDSAP) EN ISO 13485:2016	0085649-03 0108521-02

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 **SIGNATURE:** Brian Bell Digitally signed by Brian Bell Date: 2024.03.07 07:36:46 -06'00'

PLACE: Pensacola, FL. United States of America **DATE:** 07MAR2024