Activinsights

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EU Declaration of Conformity

Medical Device Directive 93/42/EEC

1) **MANUFACTURER:** Activinsights Ltd.

ADDRESS: 6 Nene Road,
Bicton Industrial Estate
Kimbolton,
Cambridgeshire,
PE28 OLF

2) **EUROPEAN AUTHORIZED REPRESENTATIVE**: CEpartner4U BV.

ADDRESS: Esdoornlaan 13, 3951 DB Maarn, The Netherlands

(On product labels printed as:
CEpartner4U, Esdoornlaan 13, 3951 DB Maarn, The Netherlands. www.cepartner4u.com)

3) **PRODUCT(S)**

Device Name	Device Description	Product Code	UDI-DI
GENEActiv (Original)	GENEActiv (Original) Single Unit Pack	GATV04M	5065009840007
GENEActiv Charging Cradle	GENEActiv 4-way Download/Charger Cradle	GATV05	5065009840014

CLASSIFICATION: Class I Non-Sterile, Rule 1 Annex IX.

4) **ADDITIONAL INFORMATION**

MHRA Reference: 10628
Code/Term: Wearable multiple physiological parameter recorder
GMDN Description: Patient data recorder, long-term, physical activity
GMDN Code: 12391
EU Registration: NL-CA002-2021-59148
Year of CE Marking: 28th September 2020

5) **STATEMENT**

This declaration of conformity is issued under the sole responsibility of the manufacturer Activinsights Ltd.

We hereby declare that the device listed above is Class I n/s and conforms with the appropriate requirements of Annex I of the Medical Device Directive 93/42/EEC, as amended by Directive 2007/47/EC. The product has been developed to in accordance with to ISO 13485:2016

The product is also registered with the MHRA in the United Kingdom as a Class I device.

6) HARMONISED STANDARDS

Harmonised Standard	Description
BS EN ISO 14971:2019	Medical devices. Application of risk management to medical devices.
BS EN 62366-1:2015	Medical devices. Application of usability engineering to medical devices.
BS EN 62304:2006+A1:2015	Medical device software – Software life-cycle processes
BS EN 60601-1-6:2010+A1:2015	Medical electrical equipment. General requirements for basic safety and essential performance. Collateral standard. Usability
ISO 10993-1:2018	Biological evaluation of medical devices. Evaluation and testing within a risk management process.
BS EN 20:2008 + A1:2013	Information supplied by the manufacturer of medical devices.
BS EN ISO 15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements.
Directive 2011/65/EU (RoHS)	The restriction of the use of certain hazardous substances in electrical and electronic equipment.

7) NOTIFIED BODY

We further declare that there is no notified body intervention required for the review of this device and the conformity assessment procedure is according to Annex VII of the Medical Device Directive.

8) DECLARATION SIGNATURE

Kimbolton, UK, 20-Mar-2024

(Place & Date of issue (yyyy-mmm-dd)

Richard Thomas, Executive Chairman

(name: function and signature of manufacturer)

Rev No	Date	Comment	Author
1.0	20/Nov/2020	Initial Release	Richard Thomas
2.0	14/Mar/2021	Updated to include EU Authorised Rep	Richard Thomas
3.0	13/Oct/2022	Updated to include applicable Standards	Richard Thomas
4.0	04/Jan/2024	Updated DOC to remove discontinued products and updated the GMDN Code	Manjit Singh
5.0	20/Mar/2024	Updated DOC for manufacturing facility address change.	Manjit Singh