




Declaration of Conformity – PRO-Diary

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

MANUFACTURER		AUTHORISED REPRESENTATIVE	
Name of Company	Address	Name of Company	Address
CamNtech Limited	Riband House Manor Farm Fenstanton Cambridgeshire PE28 9JD, UK	Qarad EC-REP BV	Pas 257 2440 Geel Belgium
SRN: TBA		SRN: BE-AR-000000040	
PRODUCT IDENTIFICATION			
Product Name	Catalogue No.	Basic UDI-DI	
PRO-Diary	05-111	++B329PDM01XT	
PRO-Diary V	05-121		
Intended Purpose		Representative Photos	
<p>The PRO-Diary is a compact, lightweight, body-worn activity monitoring device that may be used to document physical movement associated with applications in physiological monitoring. The device is intended to monitor limb or body movements during daily living and sleep. The PRO-Diary can be used to assess activity in any instance where quantifiable analysis of physical motion is desired.</p>			
RISK CLASS FOR MEDICAL DEVICES			
<p>Class 1 (active, non-measuring, non-sterile) Annex VIII of regulation 2017/745; rules 1, 13 Conformity Assessment: Annex II and Annex III of regulation 2017/745</p>			

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

- Medical Device Regulation (MDR) 2017/745
- RoHS Directive 2011/65/EU
- WEEE Directive 2012/19/EU

COMPANY REPRESENTATIVE: Howard Smith

TITLE: Director

SIGNATURE:

PLACE: United Kingdom

DATE: 05/01/2021