

EC Declaration of Conformity

Manufacturer:

iTs Designs Ltd
 (T/A: Alert-iT Care Alarms)
 Fernie House (Unit 3)
 Jackson Street
 Coalville Business Park
 Leicestershire, UK
 LE67 3NR



Issue Date	30/09/2019	Updated: 27/11/2020
Device(s)	P194B	Pulse Companion
Accessories	P195A P137 P155B	Armband Sensor Professional Pager Connect-iT
Description	The Pulse Companion is a wireless device used to alert carers when changes in the armband's heartrate reading have crossed set thresholds.	
QMS	93/42/EEC 2014/53/EU 2011/65/EU + 2015/863 2012/19/EU	Medical Device Directive (MDD) Radio Equipment Directive (RED) Permitted Materials (RoHS) Waste Electrical and Electronic Equipment Directive (WEEE)
Directives	Medical Device: Class 1	
Classification	ISO 13485	
Standards Applied	EN 14971:2019 EN 60601-1:2006+A12:2014 EN 60601-1-2:2015 EN 62366-1:2015+A1:2020 EN 12182:2012 EN 300 220-2 v3.2.1 (2018-06) EN 300 328 V2.1.1 EN 301 489-3 v2.1.1 (2019-03) EN 62368-1: 2020 +A11:2020 ISO 22196:2011	Medical Device: Risk Management Medical Device: Basic Safety Medical Device: Electromagnetic Disturbances Medical Devices applications of usability Technical Aids for Disabled Persons RED: Short Range Devices RED: Bluetooth RED: EMC RED: LVD Anti-microbial treatment

Declaration:

We declare sole responsibility that the product(s) to which this declaration relates is (are) in conformity with the relevant essential requirements set out in the above referenced EC Directive(s) and standards.

Signatory:

A handwritten signature in black ink, appearing to read 'Rick Gunn', is written over a light blue grid background.

Rick Gunn (BSc)
 Director