

EC Declaration of Conformity



Manufacturer:

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

Issue Date	30/09/2019	
Device(s)	P194B	Pulse Companion
Accessories	P195A P137 P155B	Armband Sensor Professional Pager Connect-iT / NurseCall receiver interface
Description	The Pulse Companion is a wireless device used to alert carers to changes in patient heartrate that have crossed set thresholds.	
Directives	2017/745 2014/53/EU 2011/65/EU + 2015/863 2012/19/EU	Medical Device Regulation (MDR) Radio Equipment Directive (RED) Permitted Materials (RoHS) Waste Electrical and Electronic Equipment Directive (WEEE)
Classification	Medical Device: Class 1	
QMS	ISO 13485	Medical Devices Quality System
Standards Applied	EN 14971:2012 EN 60601-1:2006+A12:2014 EN 60601-1-2:2015 EN 62366-1:2015 EN 12182:2012 EN 300 220-2 V3.1.1 EN 300 328 V2.1.1 EN 301 489-3 EN 62368-1 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 certify that the apparatus to which this declaration relates, conforms with the relevant requirements set out in the above referenced EC Directive(s) and standards, for which we have sole responsibility.

Signatory:

Rick Gunn (BSc)
Operations Director

Tony Bullars
Sales Director