

EU 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	13/07/2018	Updated: 27/11/2020
Device(s)	P164A MKII	Safelink Radio Repeater
Accessories	P171	Range of power supplies
Description	The P164 is an accessory in Safelink based radio alarm systems. It can boost the radio signal to achieve greater range or deal with difficult building topologies.	
QMS	ISO 13485	Medical Devices Quality System
Directives	2014/53/EU 2011/65/EU 2012/19/EU	Radio Equipment Directive (RED) Permitted Materials (RoHS2) Waste Electrical and Electronic Equipment Directive (WEEE)
Classification	Electrical Safety: Class II Radio Receiver: Class 2	
Standards Applied	EN 14971:2019 EN 55011:2016+A1:2017 EN 60601-1-2:2015 EN 300 220-2 v3.2.1 (2018-06) EN 60950-1:2006+A2:2013	Risk Assessment ISM Radio Disturbance Medical Device EMC Permitted radio transmissions Product Safety

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 horizontal line.

Rick Gunn (BSc)
 Director