

EC Declaration of Conformity



Manufacturer:

iTs Designs Ltd T/A Alert-iT Care Alarms
 Atherstone House
 Merry Lees Industrial Estate
 Desford
 Leicestershire LE9 9FE
 England

Issue Date	24/04/17	Updated 20/7/16
Device(s)	P168A	Bed Movement Monitor
Accessories	P153x	Power unit
Description	The P168 receives radio data from all Alert-iT radio products and can alert the user to alarms, faults and failure of the radio network	
Directives	93/42/EEC 2014/53/EU 2011/65/EU	Medical Device Directive RTT&E Directive RHOS2 Permitted Materials
Classification	Class 1 Medical Device	
Standards Applied	EN 14971:2012 EN 60601-1-2:2006+A12:2014 EN 60601-1-2:2015 EN60601-1-8:2007+A1:2013 EN62366:2015 EN55011:2016 EN 12182:2012 ISO22196 EN 300 220-1 V2.4.1(2012-05)	Risk Assessment Medical Device General Requirements Medical Device EMC Medical Alarm Systems Medical Device Usability ISM Radio Disturbance Technical Aids for Disabled Persons Anti-microbial treatment Radio Transmissions: Short Range Devices

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:

D Godfrey BSc(Hons) FIEE Ceng
 Managing Director