

EC Declaration of Conformity




Manufacturer:

iTs Designs Ltd
 Atherstone House
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 Desford
 Leicestershire LE3 3LR
 England

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| Issue Date | 21/8/2009 | updated 20/12/16 |
| Device(s) | P163ACA P163BAA P163BCA | Radio Touch-iT with Switch Input Radio Sense-iT Bed Vacation Radio Sense-iT Switch Input |
| Accessories | P160 P143C P143G P144C P149A,B P171 P159B P145 Miscellaneous switch devices | NiMH Battery, Size AA, 1.25v Bed Mat Occupancy Sensor Bed Ribbon Occupancy Sensor Bed Leg Occupancy Sensor Chair Occupancy Sensor Range of power supplies Bed/Wall Mounting Bracket Range of Nurse Call Leads Passive switching devices covered by EN12182 |
| Description | The P163 models cover a range of small monitors that detect abnormal conditions suggesting the user is at risk. These cover bed vacation, chair vacation, panic. The alarms are transmitted by Safelink Radio or to a connected Nurse Call or Telecare system | |
| Directives | 2014/53/EU 2011/65/EU | RTT&E Directive Permitted Materials (UK) |
| Classification | Safety Class II | |
| Standards Applied | EN 14971:2012 EN 60950-1:2006+A2:2013 EN 60601-1-2:2015 EN 60601-1-8:2007+A1:2013 EN 55011:2016 EN 12182:2012 EN 300 220-1 V2.4.1(2012-05) | Risk Assessment Safety Medical Device EMC Medical Device Alarms ISM Radio Disturbance Assistive Technology 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

Signatory:



D Godfrey BSc(Hons) FIEE Ceng