

EC Declaration of Conformity



Manufacturer:

iTs Designs Ltd
 Atherstone House
 Merry Lees Industrial Estate
 Desford
 Leicestershire LE3 3LR
 England

Issue Date	21/8/2009	updated 19/12/16
Device(s)	P163BBA	Radio Enuresis Alarm
Accessories	P160 P141E P142A P142 P113 P159B P145	NiMH Battery, Size AA, 1.25v Connecting Cable Instant Moisture Sensor Absorbent Moisture Sensor High protection power supplies Bed/Wall Mounting Bracket Range of Nurse Call Leads
Description	The P163 models cover a range of small monitors that detect moisture on a sensing sheet suggesting the user is at risk. 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 55011:2016 EN12182:2012 EN 300 220-1 V2.4.1(2012-05) EN60601-1-8:2007+A1:2013	Risk Assessment Safety Medical Device EMC ISM Radio Disturbance Assistive Technology Radio Transmissions: Short Range Devices Medical Device Alarms

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
 Managing Director