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 24/4/17
Device(s)	P176A	Bed Movement Monitor
. ,	P176B	Remote Reset Button
Accessories	P168	Pager
	P137	Pager
	P117C	Radio Linked Autodialler
	P155A	Infrastructure Interface
Description	The P176 Detects bed movement and sends a failsafe alarm by radio if this exceeds a preset	
	value for longer than a preset time.	
Directives	93/42/EEC	Medical Device Directive
	2014/53/EU	RTT&E Directive
	2011/65/EU	RHOS2 Permitted Materials
Classification	Class 1 Medical Device	
Standards	EN 14971:2012	Risk Assessment
Applied	EN 60601-1:2006++A12:2014	Medical Device General Requirements
	EN 60601-1-8:2010+A1:2015	Medical Device Alarm Systems
	EN62366:2015	Product Usability Engineering
	EN12182:2012	Technical Aids for Disabled Persons
	EN 60601-1-2:2015	EMC
	EN55011:2016	ISM Radio Disturbance
	EN 300 220-1 V2.4.1(2012-05)	Radio Transmissions: Short Range Devices
	ISO22196:2011	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:

D Godfrey BSc(Hons) FIEE Ceng Managing Director