

EU Declaration of Conformity

Manufacturer:

iTs Designs Ltd.
 (T/A: Alert-iT Care Alarms)
 Fernie House (Unit 3)
 Coalville Business Park
 Coalville, Leicestershire
 LE67 3NR, England
 Tel: +44 (0) 1530 239 900
 Single Registration Number (SRN): GB-MF-000027859

European Authorised Representative:

Leisner ApS
 Korsvangcentret
 DK-5610 Assens
 Denmark
 Tel: +45 6371 3050
 Single Registration Number (SRN): DK-AR-000027183


Description:	The P200 bedside monitor uses a range of small sensors to detect abnormal conditions occurring in a bed that may indicate a seizure. The alarm notifications are transmitted via Alert-iT's Safelink radio protocol or via a wired output to a connected Nurse Call or Telecare system.	
Directives:	2017/745 2014/53/EU 2011/65/EU + 2015/863 2012/19/EU	Medical Device Regulation (MDR) Radio Equipment Directive (RED) Permitted Materials (RoHS) Waste Electrical and Electronic Equipment Directive (WEEE)
Standards Applied:	BS EN 60601-1:2006+A1:2013 BS EN 60601-1-2:2015 BS EN 60601-1-6:2010 BS EN 60601-1-8:2007+A11:2017 BS EN 60601-1-11:2015 EN 300 220-2 v3.1.1 EN 300 220-3-1 v2.1.1 EN 300 328 v2.1.1	Medical Equipment: General requirements Medical Equipment: Electromagnetic disturbances Medical Equipment: Usability Medical Equipment: Alarm systems Medical Equipment: Home healthcare Radio Requirements (434 MHz Model) Radio Requirements (869 MHz Model) Radio Requirements (ERP and Emissions Only)

We hereby, under our sole responsibility declare, that the product listed above, is in conformity with the Medical Device Regulation (MDR) 2017/745 as a class I medical device based on Annex 8 and the relevant European harmonised standards listed above.

The product concerned has been manufactured under a quality management system (ISO 13485:2016) according to Annex 9 of MDR 2017/745 EU.

This EU declaration of conformity was written accordance to Annex 4 of the MDR, and all supporting documentation is retained at the premises of the manufacturer.

Refer to page 2 for models covered.



Date: 14/09/22

Place: Leicester, UK.

Name: Rick Gunn

Position: Director

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Models covered by this certificate;

Model:	Description:	Basic UDI-DI (GMN):	UDI-DI (GTIN-14):
P200AAA	Companion: 434 MHz, Alert-iT	506053070P200AQQ	50605307034700
P200ABA	Companion: 869 MHz, Alert-iT	506053070P200AQQ	50605307034878
P200AAB	Companion: 434 MHz, Leisner ApS	506053070P200AQQ	50605307034946
P200ABB	Companion: 869 MHz, Leisner ApS	506053070P200AQQ	50605307035004
P200AAC	Companion: 434 MHz, Picomed	506053070P200AQQ	50605307035172
P200ABC	Companion: 869 MHz, Picomed	506053070P200AQQ	50605307035240
P200BAA	Guardian: 434 MHz, Alert-iT	506053070P200BQS	50605307037398
P200BBA	Guardian: 869 MHz, Alert-iT	506053070P200BQS	50605307037466
P200BAB	Guardian: 434 MHz, Leisner ApS	506053070P200BQS	50605307037534
P200BBB	Guardian: 869 MHz, Leisner ApS	506053070P200BQS	50605307037602
P200BAC	Guardian: 434 MHz, Picomed	506053070P200BQS	50605307037770
P200BBC	Guardian: 869 MHz, Picomed	506053070P200BQS	50605307037848
P200CAA	Companion: 434 MHz, Alert-iT	506053070P200CQU	50605307039996
P200CBA	Companion: 869 MHz, Alert-iT	506053070P200CQU	50605307040022
P200CAB	Companion: 434 MHz, Leisner ApS	506053070P200CQU	50605307040190
P200CBB	Companion: 869 MHz, Leisner ApS	506053070P200CQU	50605307040268
P200CAC	Companion: 434 MHz, Picomed	506053070P200CQU	50605307040336
P200CBC	Companion: 869 MHz, Picomed	506053070P200CQU	50605307040404
P200DAA	Pulse Companion: 434 MHz, Alert-iT	506053070P200DQW	50605307042552
P200DBA	Pulse Companion: 869 MHz, Alert-iT	506053070P200DQW	50605307042620
P200DAB	Pulse Companion: 434 MHz, Leisner ApS	506053070P200DQW	50605307042798
P200DBB	Pulse Companion: 869 MHz, Leisner ApS	506053070P200DQW	50605307042866
P200DAC	Pulse Companion: 434 MHz, Picomed	506053070P200DQW	50605307042934
P200DBC	Pulse Companion: 869 MHz, Picomed	506053070P200DQW	50605307043092
P200EAA	Guardian: 434 MHz, Alert-iT	506053070P200EQY	50605307045140
P200EBA	Guardian: 869 MHz, Alert-iT	506053070P200EQY	50605307045218
P200EAB	Guardian: 434 MHz, Leisner ApS	506053070P200EQY	50605307045386
P200EBB	Guardian: 869 MHz, Leisner ApS	506053070P200EQY	50605307045454
P200EAC	Guardian: 434 MHz, Picomed	506053070P200EQY	50605307045522
P200EBC	Guardian: 869 MHz, Picomed	506053070P200EQY	50605307045690