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) - XXXXXXXX

European Authorised Representative:

LEISNER ApS
Korsvangcentret
DK-5610 Assens
Denmark
Tel: +45 6371 3050

Model:	Description:	Basic UDI-DI (GMN):	UDI-DI (GTIN-14):
P155BAAA	Connect-iT: UK PSU, Branding, 434 MHz	506053070P155BAAAP4	50605307005168
P155BBAA	Connect-iT: EU PSU, Branding, 434 MHz	506053070P155BBAAP9	50605307005236
P155BCAA	Connect-iT: AU PSU, Branding, 434 MHz	506053070P155BCAAPE	50605307005304
P155BAAB	Connect-iT: UK PSU, Branding, 869 MHz	506053070P155BAABP6	50605307005472
P155BBAB	Connect-iT: EU PSU, Branding, 869 MHz	506053070P155BBABPB	50605307005540
P155BBBA	Connect-iT: EU PSU, Branding, 434 MHz	506053070P155BBBAPC	50605307005618
P155BBBB	Connect-iT: EU PSU, Branding, 869MHz	506053070P155BBBBPE	50605307005786
P155BBCA	Connect-iT: EU PSU, Branding, 434 MHz	506053070P155BBCAPF	50605307005854
P155BBCB	Connect-iT: EU PSU, Branding, 869 MHz	506053070P155BBCBPH	50605307005922
P155BAGA	Connect-iT: UK PSU, Branding, 434 MHz	506053070P155BAGAPN	50605307006080
P155BBGA	Connect-iT: EU PSU, Branding, 434 MHz	506053070P155BBGAPT	50605307006158

Description:	The P155B is a radio receiver for alarms transmitted using the Alert-iT Safelink Protocol. On receipt of an alarm the internal relay is operated which, depending on the connecting lead used, can trigger many different Nurse Call and Telecare systems. It forms an accessory to these monitors to form a system compliant with the Medical Devices Regulation 2017/745.	
Directives:	2017/745	Medical Device Regulation (MDR)
	2014/53/EU	Radio Equipment Directive (RED)
	2011/65/EU + 2015/863	Permitted Materials (RoHS)
	2012/19/EU	Waste Electrical and Electronic Equipment Directive (WEEE)
Standards Applied:	BS EN 60601-1:2006+A12:2014	Medical Equipment: Basic Safety Requirements
	BS EN 60601-1-2:2015+A1:2021	Medical Equipment: EMC Requirements
	BS EN 60601-1-6:2010+A1:2015	Medical Equipment: Usability Requirements
	BS EN 60601-1-11:2015	Medical Equipment: Home Healthcare Requirements
	EN 300-220-2 v3.1.1	Radio Requirements

We hereby, under our sole responsibility declare, that the product listed above, is in conformity with the Medical Device Regulation (MDR) 2017/745 as an accessory to 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 and audited by BSI.

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.

Date: 01 JUNE 2021 Place: Leicester, UK. Name: RICHARD GUNN Position: DIRECTOR