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 "Companion mini" detects fine movements and sends alarm notifications via Alert-iT's failsafe Safelink™ radio protocol if the movements exceed user defined limits.	
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 60601-1-8:2007+A11:2017	Medical Equipment: Alarm Systems
	BS EN 60601-1-11:2015	Medical Equipment: Home Healthcare Requirements
	EN 300-220-2 v3.1.1	Radio Emissions (P176AA 434MHz Only)
	EN 300-220-3-1 v2.1.1	Radio Emissions (P176AB 869MHz Only)

Models covered by this certificate:

Model:	Description:	Basic UDI-DI (GMN):	UDI-DI (GTIN-14):
P176AAA	Companion mini: 434 MHz, Branding	506053070P176AALE	50605307017734
P176ABA	Companion mini: 869 MHz, Branding	506053070P176ABLG	50605307017802
P176AAB	Companion mini: 434 MHz, Branding	506053070P176AALE	50605307017970
P176ABB	Companion mini: 869 MHz, Branding	506053070P176ABLG	50605307018038
P176AAC	Companion mini: 434 MHz, Branding	506053070P176AALE	50605307018106
P176ABC	Companion mini: 869 MHz, Branding	506053070P176ABLG	50605307018274
P176AAG	Companion mini: 434 MHz, Branding	506053070P176AALE	50605307018342
P176ABG	Companion mini: 869 MHz, Branding	506053070P176ABLG	50605307018410

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 1 medical device based on Rule 13 of 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.

Signed:

Date: 20/June/2024 Place: Leicester, UK. Name: Rick Gunn Position: Director