



EU Declaration of Conformity

Manufacturer:

iTs Designs Ltd.
(T/A: Alert-iT Care Alarms)
Unit 3 Ground Floor,
Coalville Business Park,
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 P140 is an under mattress movement sensor for use with Alert-iT's bedside monitors.	
Directives:	2017/745 2011/65/EU + 2015/863 2012/19/EU	Medical Device Regulation (MDR) 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 60601-1-11:2015	Medical Equipment: General requirements Medical Equipment: Electromagnetic disturbances Medical Equipment: Usability Medical Equipment: Home healthcare

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 accessory 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: 14/12/22

Place: Leicester, UK.

Name: Joe Rider

Position: Director

Version: 1

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Models covered by this certificate;

Model:	Description:	Basic UDI-DI (GMN):	UDI-DI (GTIN-14):
P140AA	Movement Sensor: Light Weight, Alert-iT.	506053070P140AR5	50605307027184
P140BA	Movement Sensor: Medium Weight, Alert-iT.	506053070P140BR7	50605307027252
P140CA	Movement Sensor: Heavy Weight, Alert-iT.	506053070P140CR9	50605307027320
P140AB	Movement Sensor: Light Weight, Leisner	506053070P140AR5	50605307027498
P140BB	Movement Sensor: Medium Weight, Leisner.	506053070P140BR7	50605307027566
P140CB	Movement Sensor: Heavy Weight, Leisner.	506053070P140CR9	50605307027634
P140AC	Movement Sensor: Light Weight, Picomed.	506053070P140AR5	50605307027702
P140BC	Movement Sensor: Medium Weight, Picomed.	506053070P140BR7	50605307027870
P140CC	Movement Sensor: Heavy Weight, Picomed.	506053070P140CR9	50605307027948