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Ty Menter Navigation Park Abercynon Mountain Ash CF45 4SN

## **UKCA Declaration of Conformity**

We, Thermetrix Limited, declare under our sole responsibility that the following product:

Product and Trade Name: Podium Pro®

Product Category: Liquid crystal thermography system

Model / Product Code: P1

Single Registration Number (SRN) (from 26/05/2020 onwards) UDI-ID: 50607350400280

Risk Classification for MDR: Class I

Intended Purpose: Thermal pattern tracker for feet

Supplied Accessories: Android tablet

to which this declaration relates, has been demonstrated to fulfil the objectives referred to in the listed sections of the following UK Statutory Instruments, \* as amended:

SI 2023 No. 627 - Medical device regulations

SI 2012 No. 3032\*- Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment

SI 2017 N 1206\*- The Radio Equipment Regulations 2017

## **Designated Standards:**

EN 60601-1-2:2006+A2:2021 (EMC of Medical electrical equipment)
EN 62368-1:2018 (Audio and Visual Safety requirements)

EN62304:2006+A1:2015 (Med. Device Software Lifecycle)

EN 10993-1:2020 (Biological evaluation)

EN 55032:2015+A1:2020 (EMC - Emissions of Multimedia Equipment)
EN 55035:2017+A11:2020 (EMC - Immunity of Multimedia Equipment)
ETSI EN 301 489-1 V2.2.3:2019 (EMC - Common Technical Requirements)

ETSI EN 301 489-17 V3.1.1:2017 (EMC for Broadband Data transmission Systems)

EN 60601-1-2:2006+A2:2021 (EMC - Med. Electrical equipment)

EN 300 328 v2.1.2 (Radio Spectrum - Wideband Transmissions)

EN IEC 63000:2018 (RoHS Assessment Technical Documentation)

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Peter Plassmann 4477C8741BE7475...

Signed for and on behalf of Thermetrix Ltd.

Dr. Peter Plassmann, CTO

