EU DECLARATION OF CONFORMITY

This declaration contains 2 pages

Manufacturer: **e-TakesCare**
Headquarter: 35, rue des Chantiers
78000 Versailles - France

Declares that:

Product: smart thermometer TUCKY-21 and its variants TUCKY-21W, e-Torm TC1, TUCKY-21Y, TUCKY-21O, TUCKY-21P, TUCKY-21B and TUCKY-21N,

And accessory: adhesives ADH-21 and ADH-21B and their variants ADH-21-P1, ADH-21-E1, e-Torm ADH15, e-Torm ADH15-E1, ADH-21B-P1, ADH-21B-E1, e-Torm ADH15B, e-Torm ADH15B-E1

is in conformity with the relevant Union harmonisation legislation:

- Council directive **93/42/EEC** of 14 June 1993 concerning medical devices

- Directive **2014/53/EU** of the European Parliament and of the council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of **radio equipment** and repealing Directive 1999/5/EC

- Directive **2011/65/EU** of the European parliament and of the council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

and with the requirements of the following quality standards:

- **NF EN ISO 13485: 2016** - Quality Management System.
- **NF EN ISO 80601-2-56:2017 / ISO 80601-2-56:2017** - Medical electrical equipment: Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement.
- **NF EN ISO 14971:2019 / ISO 14971:2019 -** Medical devices - Application of risk management to medical devices.
- **NF EN 62366-1:2015 / IEC 62366-1:2015 -** Usability engineering.
- **NF EN 60601-1:2006+A1:2013 / IEC 60601-1:2005+A1:2012**- Medical electrical equipment: Part 1: General requirements for basic safety and essential performance
- **NF EN 60601-1-2:2015 / IEC 60601-1-2:2014-** Medical electrical equipment: Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.
- **ETSI EN 301 489-1 V2.2.0:2017** – ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU
- **ETSI EN 301 489-17 V3.2.0:2017** - ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU
- **IEC 62479:2010** - Assesment of the compliance of low-power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)

- **NF EN 60601-1-11:2015 / IEC 60601-1-11:2015** - Medical electrical equipment: Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
- **NF EN 62304:2006/AMD1:2015 / IEC62304:2006/AMD1:2015 -** Medical device software - Software life-cycle processes.
- **NF EN ISO 10993-1:2009 / ISO 10993-1:2009** - Biological evaluation of medical devices: Part 1: Evaluation and testing within a risk management process.
- **NF EN ISO 10993-5:2009 / ISO 10993-5:2009** - Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- **NF EN ISO 10993-10:2013 / ISO 10993-10:2013** - Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- **NF EN ISO 15223-1:2016 / ISO 15223-1:2016 -** Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied. Part 1: General requirements.
- **NF EN 1041: 2008 + A1:2013 -** Information supplied by the manufacturer of medical devices.
- **ETSI EN 300 328 V2.1.1 –** Bluetooth.
- **IEC 62133:2012** – Battery certificate
- **Meddev 2.7/1 rev 04: 2016 -** Clinical evaluation: a guide for manufacturers and notified bodies
- **ASTM E1112-00:2011:** Standard Specification For Electronic Thermometer For Intermittent Determination Of Patient Temperature

CE marking was affixed after certification of E-TakesCare quality assurance system according to the annex II (excluding paragraph 4): certificate N° IT269883 - 1, valid until 2022/09/01 from Notified Body Bureau Veritas Italia S.p.A. EC Number 1370 – Viale Monza, 347 -20126 Milan, Italy.

Issued by e-TakesCare in Versailles, France

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Date: 24/07/2020