Innokas Medical

Declaration of Conformity

We

Innokas Yhtymä Oy
Vihikari 10,
FI-90440 Kempele
FINLAND

declare under our sole responsibility that the

CARESCAPE VC150 Vital Signs Monitor
Medical device classification IIb according to rule 10 set out in Annex IX of Directive 93/42/EEC
Conformity assessment procedure: Annex II (excluding Section 4)
GMDN 36872: Patient monitor, multiparameter, transportable

is in conformity with the applicable provisions of Council Directive 93/42/EEC as amended by 2007/47/EC concerning medical devices

and The Radio Equipment Directive (2014/53/EU)

and Directive 2011/65/EU of the European Parliament of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

and Council Recommendation (1999/519/EC) of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz),

and the product is in conformity with the following standards:

- IEC 60601-1 ed3.1 (2012) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2 ed. 4.0 (2014) Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- IEC 60601-1-6 ed3.0 (2010)/Amd1: 2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- IEC 60601-1-8 ed2.0 (2006) Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- ISO 10993-1:2009 ed4 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- IEC 60601-2-49 ed2.0 (2011) Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
- 80601-2-30:2009/Amd 1:2013 Medical electrical equipment - Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- ISO 80601-2-61 ed1.0 (2011) Medical electrical equipment – Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
- ISO 80601-2-56 ed1.0 (2009) Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
- EN ISO 14971:2012 Medical devices. Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
- IEC 62304 ed1.0 (2006) Medical device software - Software life cycle processes

- IEC 62366 ed1.0 (2007)/Amd 1:2014 Medical devices - Application of usability engineering to medical devices
- ISO 81060-2 ed2 (2013) Non-invasive sphygmomanometers - Part 2: Clinical investigation of automated measurement type
- EN ISO 9919 (2009) Medical electrical equipment – Particular requirements for basic safety and essential performance of pulse oximeter equipment for medical use.
- ASTM E1112 - 00 (2011) Standard Specification for Electronic Thermometer for Intermittent Determination of Patient Temperature
- ANSI/AAMI ES60601-1:2005/(R)2012 includes A1:2012, C1:2009/(R)2012, and A2:2010/(R)2012 Medical electrical equipment, Part 1: General requirements for basic safety and essential performance
- CAN/CSA-C22.2 NO 60601-1-08 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (Adopted IEC 60601-1:2005, third edition, 2005-12, including amendment 1:2012, with Canadian deviations)
- ISTA Procedure 2A: 2011 Packaged-Products weighing 150 lb (68 kg) or Less (Basic Requirements: atmospheric conditioning, compression, fixed displacement or random vibration and shock testing)
- UL 60601-1 First Edition April 2003 (with revisions through and including April 2006) Medical Electrical Equipment, Part 1: General Requirements for Safety
- UL 94 edition 6 (2013) Standard for Tests for Flammability of Plastic Materials for Parts in Devices and Appliances
- EN 301 893 (v1.8.1) Broadband Radio Access Networks (BRAN); 5 GHz high performance RLAN; Harmonized EN covering the essential requirements of article 3.2 of Directive 2014/53/EU
- ETSI EN 301 893 (V2.1.0 clause 4.2.8) 5 GHz RLAN; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
- EN 300 328 (v2.1.1) Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU
- EN 301 489-17 (v3.1.1) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems
- EN 301 489-1 (v2.1.1) Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
- EN 50581 (2012) Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
- IEC 62311 (2007) Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)

The Notified body is SGS Fimko Oy, 0598
Takomotie 8
FI-00380 Helsinki,
Finland
EC certificate number FI14/07007

January 29th 2021
On behalf of Innokas Yhtymä Oy,

Janne Kostamo
CEO
Innokas Yhtymä Oy