

## Declaration of Conformity

We

Innokas Yhtymä Oy  
Vihikari 10,  
FI-90440 Kempele  
FINLAND

certify 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 ed3.0 (2007) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - 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
- IEC 60601-2-30:2009/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
- ISO 14971:2007 Medical devices -- Application of risk management to medical devices
- 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  
P.O. Box 30 (Särkiniementie 3)  
Helsinki, FI-00211  
Finland

August 17<sup>th</sup> 2017  
On behalf of Innokas Yhtymä Oy,

  
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Jouni Toijala  
CEO  
Innokas Yhtymä Oy