EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC, Annex II)

We

Manufacturer

GE Healthcare Finland Oy
Kuortaneenkatu 2
FI-00510 Helsinki, Finland

Declare under our sole responsibility that the class IIb device:

Product Description	Catalog Designation
CARESCAPE Bx50 V3 U-SW	5514034-01

GMDN Code: 59378
An individual software application program or group of programs intended to provide clinical management information for a patient being monitored by a single-patient physiologic monitoring system. It provides the ability to continually detect, measure, and display multiple physiological parameters associated with a single-patient, typically bedside or in an acute care setting. It typically includes visible and/or audible signal/alarm features and monitored parameters such as electrocardiogram (ECG), blood pressure, heart rate, temperature, cardiac output. A basic set of application programs and routines are included with the system that can be upgraded to add new system capabilities.

Classification rule (93/42/EC Annex IX): 10

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it.

This conformity is based on the following elements:

Information included in the documents:

- Technical Documentation Ref.: CARESCAPE Bx50 V3 U-SW Technical File DOC2361050 of the product to which this declaration relates, for design, verification and manufacturing of the device.
- EC certificate: approval of full quality assurance system (Annex II of the medical devices directive 93/42 EEC) delivered by Eurofins Expert Services (Notified Body no. 0537) on 6th September 2019 / Certificate no. C-01-1004-698-19
- List of standards applied for CE marking as in Appendix 1

Helsinki, 12 March 2020

Rauno Ruoho
Regulatory Affairs Director

This EC Declaration of Conformity is initial revision.

Appendix 1

Relevant Standards
IEC 62304: 2006 + A1: 2015: Medical device software – Software life cycle processes
IEC 60601-1-6: 2010, A1: 2013: Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
IEC 62366-1: 2015: Medical devices - Application of usability engineering to medical devices
IEC 60601-1-8: 2006 + A1: 2012: 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
IEC 60601-2-25:2011: Medical Electrical Equipment Part 25: Particular Requirements for the Safety and essential performance of Electrocardiographs
IEC 60601-2-26:2012: Medical electrical equipment - Part 2-26: Particular requirements for the safety and essential performance of electroencephalographs
IEC 60601-2-27: 2011: Medical electrical equipment - Part 2-27 Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment
IEC 80601-2-30: 2009, A1: 2013: Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
IEC 60601-2-34:2011: Medical Electrical Equipment - Part 2-34: Particular Requirements for the basic safety and essential performance, of Invasive Blood Pressure Monitoring Equipment
IEC 60601-2-40:2016: Medical Electrical Equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment
IEC 60601-2-49:2011: Medical electrical equipment - Part 2-49: Particular requirements for the safety essential performance of multifunction patient monitoring equipment
ISO 80601-2-55: 2011: Medical electrical equipment - Part 2-55: Particular requirements for the basic safety and essential performance of respiratory gas monitors.
ISO 80601-2-56: 2009: Medical electrical equipment - Part 2-56: Particular requirements for the basic safety and essential performance of clinical thermometers for body temperature measurement.
ISO 80601-2-61: 2011: Medical electrical equipment - Part 2-61: Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
EN 1041:2008, A1:2013: Information supplied by the manufacturer of medical devices
EN ISO 14971:2012 Medical devices — Application of risk management to medical devices