GE Healthcare

EC DECLARATION OF CONFORMITY

(Following the provisions of the medical devices directive 93/42/EEC, Annex II)
(Following the provisions of the RoHS directive 2011/65/EU, Articles 7, 13 and Annex VI)

We

Manufacturer:
GE Healthcare Finland Oy
Kuortaneenkatu 2
00510 Helsinki
Finland

Declare under our sole responsibility that the class IIb device:

CARESCAPE Monitor B650

A unit that, utilizing built-in functions, modules or other equipment, collects several monitoring parameters and displays these by the bed/patient. A bedside unit can be coupled up to a central unit, but can operate independently. The monitoring parameters can be, e.g. electrocardiogram (ECG), blood pressure, temperature, cardiac output or respiration gases.

REF: 2068487-001

GMDN Code: 33586

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 and with the requirements of the RoHS Directive 2011/65/EU, Article 4.

This conformity is based on the following elements:

Information included in the documents:

- Technical Documentation Ref.: CARESCAPE Monitor B650 Technical File (DOC1271276)
- EC Certificate: Approval of full quality assurance system (Annex II of the medical devices directive 93/42/EEC) delivered by VTT Expert Services Ltd (Notified Body no. 0537) on 08 May 2015 / Certificate N° VTT-C-11340-01-1004-543-15
- List of standards applied for CE marking as in Appendix 1

Helsinki, 17 June 2015

Rauno Ruoho
Regulatory Affairs Director

This EC declaration of conformity is the fourth version for this product and replaces the previous dated 04-June-2015. This EC declaration of conformity is applicable to production units with serial number SEW14257957HA and later and serial numbers

SEW14010122HA	SEW14019943HA	SEW14019952HA	SEW14019962HA	SEW14019976HA
SEW14010123HA	SEW14019944HA	SEW14019954HA	SEW14019963HA	SEW14019977HA
SEW14010124HA	SEW14019945HA	SEW14019955HA	SEW14019964HA	SEW14019978HA
SEW14010125HA	SEW14019946HA	SEW14019956HA	SEW14019967HA	SEW14019979HA
SEW14010126HA	SEW14019947HA	SEW14019957HA	SEW14019968HA	SEW14019980HA
SEW14010127HA	SEW14019948HA	SEW14019958HA	SEW14019969HA	SEW14019981HA
SEW14010128HA	SEW14019949HA	SEW14019959HA	SEW14019971HA	SEW14019982HA
SEW14010129HA	SEW14019950HA	SEW14019960HA	SEW14019973HA	
SEW14010130HA	SEW14019951HA	SEW14019961HA	SEW14019975HA	

Relevant Standards
EN 60601-1:1990+ A1:1993 + A2:1995 + A13:1996: Medical electrical equipment — Part 1: General requirements for safety
EN 60601-1-1:2001: Medical electrical equipment — Part 1-1: General requirements for safety — Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-2:2001 + A1:2006: Medical electrical equipment — Part 1-2: General requirements for safety — Collateral standard: Electromagnetic compatibility — Requirements and tests
EN 60601-1-4:1996 + A1:1999: Medical electrical equipment — Part 1-4: General requirements for safety — Collateral standard: Programmable electrical medical systems
EN 60601-1-6:2007 +AC:2010: Medical electrical equipment — Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability
EN 60601-1-8:2007+AC:2010: 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
EN 60601-2-10:2000 + A1:2001: Medical electrical equipment — Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
EN 60601-2-25 + A1:1995: Medical electrical equipment — Part 2-25: Particular requirements for the safety of electrocardiographic
EN 60601-2-26:2003: Medical electrical equipment — Part 2-26: Particular requirements for the safety of electroencephalographs
EN 60601-2-27+AC:2006: Medical electrical equipment — Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment
EN 60601-2-30:2000: Medical electrical equipment — Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
EN 60601-2-34:2000: Medical electrical equipment — Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment
EN 60601-2-40:1998 Medical electrical equipment — Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment
EN 60601-2-49:2001: Medical electrical equipment — Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
EN 60601-2-51:2003 Medical electrical equipment — Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs
EN 1060-1:1995 + A2:2009: Non-invasive sphygmomanometers — Part 1: General requirements EN 1060-3:1997 + A2:2009: Non-invasive sphygmomanometers — Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems Except for: Clause 7.9 failed by PDM module: Testing performed in accordance with EN 1060-4
EN ISO 9919:2009: Medical electrical equipment — Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use
EN 12470-4:2000 + A1:2009 Clinical thermometers — Part 4: Performance of electrical thermometers for continuous measurement Except for: Clause 6.3 b) Temperature measurement error with single use probes exceeded maximum permissible error. Clause 6.4 The response time of the Esophageal stethoscope with temperature probe exceeds 150s for the probe sizes 18F and 24F.
EN ISO 21647:2009: Medical electrical equipment — Particular requirements for the basic safety and essential performance of respiratory gas monitors
EN ISO 14971:2012 Medical devices — Application of risk management to medical devices (ISO 14971:2007(E))
EN 1041:2008: Information supplied by the manufacturer of medical devices
EN 980:2008 Symbols for use in the labeling of medical devices
EN 62366:2008 Medical Devices- Application of usability to medical devices
EN 62304:2006 Medical device software – Software life cycle processes