EC Declaration Of Conformity

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EC REP
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The Netherlands

Notified Body 0123
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 München, Germany

PHYSIO-CONTROL declares that the CE marked product

ITEM
LIFEPAK® 15 Monitor/Defibrillator
battery powered with external power and Internal Paddles capability

PART NUMBERS
V15-2-XXXXXX

Conforms to European Community Council Directive 93/42/EEC (Medical Device Directive), as amended through 2007/47/EEC, and is a Class IIb Device assessed under Annex II. As such, the CE marked product complies with the following standards:

STANDARDS	SUBJECT
EN 1041:2008	Requirements for information supplied by medical device manufacturers
EN 1060-1:1995 + A1	General safety requirements for sphygmomanometers
EN 1060-3:1997	Supplementary requirements for electro-mechanical sphygmomanometers
EN 1789:2007 *	Safety requirements for ambulances and their equipment
EN 9919:2009	Safety and performance requirements for medical pulse oximeters
EN 12470-4:2000	Performance requirements for clinical thermometers
EN 21647:2009	Safety and performance requirements for respiratory gas monitors
EN 60601-1:1990 + A1/ A2	General requirements for safety for medical electrical equipment
EN 60601-1-1:2001	Safety requirements for electromedical systems
EN 60601-1-2:2001 + A1*	EMC requirements for medical electrical equipment
EN 60601-1-4:1996 +A1	Safety requirements for programmable electromedical systems
EN 60601-1-6:2004	Safety requirements for usability
EN 60601-1-8:2004 +A1	Safety requirements for alarm systems
EN 60601-2-4:2003	Safety requirements for cardiac defibrillators
EN 60601-2-25:1995 + A1	Safety requirements for electrocardiographs
EN 60601-2-30:2000	Safety and performance requirements for non-invasive blood pressure monitors
EN 60601-2-34:2000	Safety and performance requirements for invasive blood pressure monitors
EN 60601-2-49:2001	Safety requirements for multifunction patient monitoring equipment

Included are the following accessories:

Power Source
- Li-Ion battery
- AC & DC power adapters

Therapy
- Hard paddle electrodes
- QUIK-COMBO™ pacing/defibrillation/ECG electrodes
- QUIK-COMBO RTS pacing/defibrillation/ECG electrodes
- QUIK-COMBO PEDIATRIC pacing/defibrillation/ECG electrodes
- QUIK-COMBO REDI-PAK™ pacing/defibrillation/ECG electrodes
- QUIK-COMBO Therapy cable
- QUIK-COMBO Test Load
- Pediatric paddle adapter
- Cable-Adapter, LP15 to LP12 Internal Paddles
- LIFEPAK Internal Paddles

ECG Monitoring
- 3-wire ECG cable
- 5-wire ECG cable
- 12-lead ECG cable

Non-Medical Accessories
- Serial communication cable
- Internal Bluetooth meets Directives 1995/5/EC, and 89/336/EEC
- LIFENET Gateway
- Attachment Kit, LP15 Power Adapter **

SpO_2 Monitoring (Masimo)
- Patient extension cables LNOP (4 foot, 8 foot, 12 foot) and LNCS (4 foot, 10 foot, 14 foot)
- Reusable LNOP,LNCS and M-LNCS sensors
- Disposable LNOP,LNCS and M-LNCS sensors
- Disposable LNOP,LNCS and M-LNCS sensor sample kits
- MNC Adapter Cable (4 & 10 foot)

SpO_2 Monitoring, SpCO and SpMet (Masimo)
- Rainbow patient extension cables
- Rainbow reusable sensors
- Rainbow disposable sensors
- Rainbow light shields
- Red MNC cable with compatible Nellcore Sensors

NIBP Monitoring (CAS Medical Systems or Statcorp Medical)
- NIBP reusable blood pressure cuffs
- NIBP disposable blood pressure cuffs
- NIBP hoses

$EtCO_2$ Monitoring (Oridion Systems)
- EtCO2 FilterLines
- EtCO2 Smart Capnolines

IP Monitoring
- 5 µV/V/mm Hg transducers compliant with IEC 60601-2-34 and AAMI BP-22

Temperature Monitoring (Measurement Specialties)
- types 4491 and 4499HD temperature probes
- adapter cable (5 & 10 foot)

Signed July 17, 2012
Redmond, WA

Paula Lank
Vice President, Regulatory Affairs

This declaration is issued under the sole responsibility of the manufacturer. This declaration applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

* As modified by EN 60601-2-4; EN 60601-2-25; EN 60601-2-27; EN 60601-2-30; and EN 60601-2-49

****** ISO 1789 Safety requirements for ambulances and their equipment not applicable to the power adapter attachment kit.