EC Declaration Of Conformity

CE 0123

Physio-Control, Inc.
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EC REP
Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands

Physio-Control declares that the CE marked product

Product Name: **LIFEPAK® 15 Monitor/Defibrillator**
Part Number(s): **V15-2-XXXXXX**
ZV15-2-XXXXXX

Where X represents any numeric digit

Conforms to European Directive 93/42/EEC (Medical Device Directive) class IIb, assessed per Annex II, and complies with:

Safety:

EN 60601-1:1996/IEC 60601-1:1995
Internally powered, type BF with CF parts, IP44
IEC 60601-2-4:2002
EN 60601-2-25:1999
EN 60601-2-30/IEC 60601-2-30:1999
EN 60601-2-34/IEC 60601-2-34:2000*****
EN 864:1996
EN 1060-1:2002
EN 1060-3:1997
EN 1041:1999
EN 1789:1999/A1:2003
ISO 9919:2005

EMC:

EN 60601-1-2:2004******; IEC 60601-1-2:2004 (Ed. 2.1)
EN 60601-2-4:2003******; IEC 60601-2-4:2002 (2nd Ed.)
CISPR11:2004 Class B, Group 1; CISPR11:2003 w/AMD1:2004 & AMD2:2006, Class B, Group 1
EN 61000-4-2/IEC 61000-4-2:2001; 6 kV CD, 8 kV AD
EN 61000-4-3/IEC 61000-4-3:2006 w/AMD1:2007; 3 V/m, 10 V/m, & 20 V/m
EN 61000-4-6/IEC 61000-4-6:2003 w/AMD1:2004 & AMD2:2006; 3 Vrms outside ISM bands, 10 Vrms inside ISM bands
IEC 61000-4-8:2001 3A/m, 10 A/m

*****When used with IP transducers compliant with IEC 60601-2-34
******See EMC tables in operating instructions

Included are the following accessories:

Power Source
- Li-Ion battery

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

Non-Medical Accessories
- Serial Communication Cable

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

12-lead ECG cable (includes main cable, limb lead attachment, and precordial lead attachment)

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

SpO_2 Monitoring, SpCO and SpMet (Masimo)
- Rainbow patient extension cables
- Rainbow reusable sensors
- Rainbow disposable sensors

NIBP Monitoring (CAS Medical Systems)
- 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

Internal Bluetooth 311i serial port adapter is CE certified to R&TTE Directive 1999/5/EC and EMC Directive 89/336/EEC

Signed March 16, 2009
Redmond, WA

Paula Lank
Vice President, Regulatory Affairs

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.