EC Declaration Of Conformity

Physio-Control, Inc.
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EC REP

Physio-Control Operations Netherlands, B.V.
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1015 CJ Amsterdam
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Notified Body 0123
TÜV SÜD Product Service GmbH
Ridlerstrasse 65
80339 München, Germany

PHYSIO-CONTROL declares that the CE marked product

ITEM	DOCUMENT NUMBER
LIFEPAK CR® Plus Defibrillator	**3200731**
LIFEPAK EXPRESS® Defibrillator	**3202177**

Conforms to European Community Council Directive 93/42/EEC (Medical Device Directive), as amended through 2007/47/EC, and is a Class IIb Device assessed under Annex II.

The CE marked product also conforms to the following EC Directives:

DIRECTIVE	SUBJECT
2012/19/EU	Waste Electrical and Electronic Equipment Directive
2006/66/EC	Battery directive, as amended through 2013/56/EU
2011/65/EU	Restriction of the use of certain hazardous substances (RoHS Directive) • Annex I – Category 8 – Medical Devices • Annex IV – Exemption 17

The CE marked product complies with the following standards:

STANDARD	SUBJECT
EN 60601-1:2006 + A11:2011	General requirements for safety for medical electrical equipment
EN 60601-1-2: 2007 + A1:2010	EMC requirements for medical electrical equipment
EN 60601-1-6: 2010	Safety requirements for usability
EN 60601-1-8:2007+CORR:2010	Tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
EN 60601-1-11:2010	Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
EN 60601-2-4:2011	Safety requirements for cardiac defibrillators
EN1041:2008+A1:2013	Information supplied by the manufacturer with medical devices
EN ISO 15223-1:2012	Symbols to be used with medical device labels, labeling and information to be supplied
EN 62366:2008	Application of usability engineering to medical devices
EN 60086-4:2008	Safety of Lithium Batteries
EN 50419:2006	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
EN 62304:2006	Medical Device Software – Software Life Cycle Processes

The CE marked product was evaluated with the following accessories:

Power Source
- CHARGE-PAK™ battery charger
- Battery charger and electrodes replacement kit

Therapy-Related Accessories
- QUIK-COMBO™ pacing/defibrillation/ECG electrodes

Separately CE Marked accessories:

Therapy-Related Accessories
- Infant/Child Reduced Energy Defibrillation Electrodes

Signed September 15, 2014
Redmond, WA

Paula Lank
Vice President | Regulatory and Clinical 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.