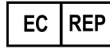




EC Declaration Of Conformity



Physio-Control, Inc.
11811 Willows Road NE
Redmond, WA 98052 USA



**Physio-Control Operations
Netherlands, B.V.**
Galjoenweg 68,
6222 NV Maastricht
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 CR® Plus Defibrillator
LIFEPAK EXPRESS® Defibrillator

DOCUMENT NUMBER
3200731-xxx (Table 1)
3202177-xxx (Table 1)

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

2012/19/EU
2006/66/EC
2011/65/EU

SUBJECT

Waste Electrical and Electronic Equipment Directive
Battery directive, as amended through 2013/56/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

EN 60601-1:2006 + A11:2011
EN 60601-1-2: 2007 + A1:2010
EN 60601-1-6: 2010
EN 60601-1-8:2007+CORR:2010

EN 60601-1-11:2010

EN 60601-2-4:2011
EN1041:2008+A1:2013
EN ISO 15223-1:2012

EN 62366:2008
EN 60086-4:2008
EN 50419:2006

EN 62304:2006

SUBJECT

General requirements for safety for medical electrical equipment
EMC requirements for medical electrical equipment
Safety requirements for usability
Tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
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
Safety requirements for cardiac defibrillators
Information supplied by the manufacturer with medical devices
Symbols to be used with medical device labels, labeling and information to be supplied
Application of usability engineering to medical devices
Safety of Lithium Batteries
Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
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
ELECTRODE ASSY- QUIK-COMBO QUIK-PAK

Separately CE Marked accessories:

Therapy-Related Accessories
Infant/Child Reduced Energy Defibrillation Electrodes

Table 1

LPCR PLUS SEMI		3200731-189	LPCR ,AUTO, SWEDISH
3200731-028	LPCR ,SEMI,INT ENG	3200731-209	LPCR ,AUTO, DANISH
3200731-048	LPCR ,SEMI, GERMAN	3200731-227	LP CR ,AUTO,PULSE,FINN
3200731-068	LPCR ,SEMI, ITALIAN	3200731-229	LP CR ,AUTO,CIRK,FINN
3200731-088	LPCR ,SEMI, FRENCH	3200731-231	LP CR ,AUTO,BREATH, FINN
3200731-108	LPCR ,SEMI, DUTCH	3200731-249	LPCR ,AUTO, NORWEGIAN
3200731-128	LPCR ,SEMI, SPANISH	3200731-269	LPCR ,AUTO, POLISH
3200731-148	LPCR ,SEMI, PORTUGUESE	3200731-289	LP CR ,AUTO,HUNGARIAN
3200731-168	LP CR ,SEMI,BRAZ/PORT	3200731-303	LPCR ,AUTO, CZECH
3200731-188	LPCR ,SEMI, SWEDISH	3200731-329	LPCR ,AUTO,RUSSIAN
3200731-208	LPCR ,SEMI, DANISH	3200731-349	LPCR ,AUTO, CHI MAND
3200731-226	LP CR ,SEMI,PULSE,FINN	3200731-369	LPCR ,AUTO, CHI CANT
3200731-228	LP CR ,SEMI,CIRK,FINN	3200731-389	LPCR ,AUTO KOREAN
3200731-230	LP CR ,SEMI,BREATH, FINN	3200731-449	LPCR ,AUTO,GREEK
3200731-248	LPCR ,SEMI, NORWEGIAN	3200731-469	LPCR ,AUTO, HEBREW
3200731-268	LPCR ,SEMI, POLISH	3200731-507	LPCR ,AUTO,CFP,ICE
3200731-288	LP CR ,SEMI,HUNGARIAN	3200731-509	LPCR ,AUTO,CFC,ICE
3200731-302	LPCR ,SEMI, CZECH	3200731-511	LPCR ,AUTO,CFB,ICE
3200731-328	LPCR ,SEMI,RUSSIAN	3200731-525	LPCR ,AUTO, AUSTRIAN
3200731-348	LPCR ,SEMI, CHI MAND	3200731-549	LPCR ,AUTO, BRITISH
3200731-368	LPCR ,SEMI, CHI CANT	3200731-569	LPCR ,AUTO,TURKISH
3200731-388	LPCR ,SEMI, KOREAN	3200731-589	LPCR ,AUTO,SLOVAK
3200731-448	LPCR ,SEMI,GREEK	3200731-607	LPCR ,AUTO,PULSE,SLOV
3200731-468	LPCR ,SEMI, HEBREW	3200731-609	LPCR ,AUTO,CIRK,SLOV
3200731-506	LPCR ,SEMI,CFP,ICE	3200731-611	LPCR ,AUTO,BREATH,SLOV
3200731-508	LPCR ,SEMI,CFC,ICE	3200731-629	LPCR ,AUTO,LITHUANIAN
3200731-510	LPCR ,SEMI,CFB,ICE	3200731-649	LPCR ,AUTO,CATALAN SPANISH
3200731-524	LPCR ,SEMI, AUSTRIAN	3200731-703	LPCR ,AUTO,ROMANIAN,
3200731-548	LPCR ,SEMI, BRITISH		
3200731-568	LPCR ,SEMI,TURKISH	LPExpress SEMI	
3200731-588	LPCR ,SEMI,SLOVAK	3202177-027	LP EXPRESS,SEMI,INTL ENG
3200731-606	LPCR ,SEMI,PULSE,SLOV	3202177-047	LP EXPRESS, SEMI, GERMAN
3200731-608	LPCR ,SEMI,CIRK,SLOV	3202177-067	LP EXPRESS, SEMI, ITALIAN
3200731-610	LPCR ,SEMI,BREATH,SLOV	3202177-087	LP EXPRESS, SEMI, FRENCH
3200731-628	LPCR ,SEMI,LITHUANIAN	3202177-107	LP EXPRESS, SEMI, DUTCH
3200731-648	LPCR ,SEMI,CATALAN SPANISH	3202177-127	LP EXPRESS, SEMI, SPANISH
3200731-702	LPCR ,SEMI,ROMANIAN,	3202177-147	LP EXPRESS, SEMI, PORTUGUESE
		3202177-167	LP EXPRESS, SEMI, BRAZ PORT
LPCR PLUS AUTO		3202177-187	LP EXPRESS, SEMI, SWEDISH
3200731-029	LPCR ,AUTO,INT ENG	3202177-207	LP EXPRESS, SEMI, DANISH
3200731-049	LPCR ,AUTO, GERMAN	3202177-247	LP EXPRESS, SEMI, NORWEGIAN
3200731-069	LPCR ,AUTO, ITALIAN	3202177-267	LP EXPRESS, SEMI, POLISH
3200731-089	LPCR ,AUTO, FRENCH	3202177-287	LP EXPRESS, SEMI, HUNGARIAN
3200731-109	LPCR ,AUTO, DUTCH	3202177-327	LP EXPRESS, SEMI, RUSSIAN
3200731-129	LPCR ,AUTO, SPANISH	3202177-387	LP EXPRESS, SEMI, KOREAN
3200731-149	LPCR ,AUTO, PORTUGUESE	3202177-445	LP EXPRESS, SEMI, GREEK ROHS
3200731-169	LP CR ,AUTO,BRAZ/PORT	3202177-523	LP EXPRESS, SEMI, AUSTRIA

Signed January 27, 2015
 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.