



EC Declaration Of Conformity



Physio-Control, Inc.
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**Physio-Control Operations
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The Netherlands

PHYSIO-CONTROL declares that the CE marked product

ITEM
Li/MnO₂ Battery 12V 4.65Ah 55Wh
Kit, Replacement, Battery,
For use with the LIFEPAK[®] CR2 AED Defibrillator

PART NUMBER
3314533-004
3323374-004

Conforms to European Council Directive 93/42/EEC (Medical Device Directive), as amended through 2007/47/EC as a Class I Device assessed under Annex VII.

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

DIRECTIVE

2012/19/EU
2006/66/EC

SUBJECT

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

The CE marked product complies with the following standards:

STANDARDS

EN 60086-4: 2007
EN 1041:2008+A1:2013
EN ISO 15223-1:2012

EN 50419-:2006

EN ISO 14971:2012
EN 60601-1:2006+A12:2014

EN 60601-1-2:2007+AC:2010
EN 60601-2-4:2011
EN 60601-1-6:2010+A1:2015

EN 62366:2008+A1:2015

SUBJECT

Primary batteries Part 4: Safety of lithium batteries
Information supplied by the manufacturer of medical devices
Symbols to be used with medical device labels, labeling and information to be supplied
Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)
Medical devices – Application of risk management to medical
General requirements for safety for medical electrical equipment
Electromagnetic compatibility; requirements for test.
Particular requirements for the safety of cardiac defibrillators
General requirements for safety- Collateral Standard: Usability
Application of usability engineering to medical devices

Signed December 12, 2016
 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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn. .