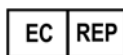




EC Declaration Of Conformity



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



Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
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® 1000 Defibrillator

PART NUMBER
3203715

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

EN 60601-1:1996 + A1/ A2

EN 60601-1-2:2001 + A1*

EN 60601-1-4:1996 +A1

EN 60601-1-6:2004

EN 60601-2-4:2003

UL 1642:2005

EN 1041:2008

SUBJECT

General requirements for safety for medical electrical equipment

EMC requirements for medical electrical equipment

Safety requirements for programmable electromedical systems

Safety requirements for usability

Safety requirements for cardiac defibrillators

Safety requirements for lithium batteries

Requirements for information supplied by medical device manufacturers

Included are the following accessories:

Power Source

Lithium primary battery (LiMnO₂)

Therapy

QUIK-COMBO™ pacing/defibrillation/ECG electrodes

QUIK-COMBO™ RTS pacing/defibrillation/ECG electrodes

QUIK-COMBO™ pacing/defibrillation/ECG electrodes with REDI-PAK™

Infant/Child reduced energy electrodes

ECG Accessory

LIFEPAK® 1000 ECG electrode cable

Non-Medical Accessories

Soft case

Signed March 24, 2011



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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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