KOPIE

CE 0123

EC DECLARATION OF CONFORMITY

Medtronic

Manufacturer's Name: Medtronic Emergency Response Systems, Inc.

Manufacturer's Address: 11811 Willows Road NE
Redmond, WA 98052-2003 USA

declares that the CE-marked product

Product Name: LIFEPAK® 500 automated external defibrillator

Model Number: 3011790 (biphasic only)

complies with 93/42/EEC (Medical Device Directive) Class IIb, conformity assessed per Annex II.

Safety: EN60601-1:1996/ IEC 60601-1:1995
internally powered, Type BF, Continuous operation.
IEC 60601-2-4:1983

EMC: EN60601-1-2:1993/IEC 60601-1-2:
EN 55011:1991- Class B, Group 1
EN61000-4-2 1st edition - 8kV CD, 15 kV AD
IEC61000-4-3 1st edition - 3 V/m
EN61000-4-4 1st edition - Not Applicable
IEC61000-4-5/EN61000-4-5 1st edition - Not Applicable

Supplementary Information:
Included are the following accessories and interconnecting cables:

QUIK-COMBO™ electrode set, PN 806086, 3008997, 3008826 or 3010188-001
FAST-PATCH® electrodes, PN 3006292 or 3010188-002
FAST-PATCH defibrillation cable, PN 3010493
Sealed lead-acid battery, PN 3005379
Lithium battery, PN 3200390, 3005380
Battery Charger (non-medical), PN 3006535
Data transfer cable (non-medical), PN 3005381
Infant/Child Reduced Energy Defibrillation Electrodes (specially configured biphasic AEDs only), PN 3202380

This product also complies with:

UL 2601-1:1994,
CSA C22.2 No. 601.1 and CSA C22.2 No. 601.2.4,
AAMI ES1, AAMI DF39

Michael D. Willingham
Vice President, Regulatory Affairs

Redmond, October 25, 2004

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.

Authorized EC Representative: Medtronic B.V., Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands