KOPIE

OPIS

EC DECLARATION OF CONFORMITY

CE 0123

Medtronic

OPIS

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® 20 defibrillator/monitor
Part Number(s):	3200500

complies with 93/42/EEC (Medical Device Directive) class IIb. Conformity assessed per Annex II.
This product complies with:

Safety:	EN60601-1:1996/IEC 60601-1:1995	
	CLASS I, type BF with CF parts/Continuous operation	
	IEC 60601-2-4:1983	
	EN 60601-2-25/IEC 60601-2-25:1993	
	UL 2601-1:10-24-97*	
EMC:	EN60601-1-2:1993	
	EN 55011:1991	Class B, Group 1
	EN 61000-4-2/IEC 61000-4-2:1995	3kV CD, 8kV AD
	EN 61000-4-3:1996/IEC 61000-4-3:1995	3 V/m
	EN 61000-4-4/IEC 1000-4-4:1995	0.5 kV Power Lines
	EN 61000-4-5/IEC 1000-4-5:1995	0.5 kV Power Lines and per EN 60601-1-2

*Tested according to Figure 11 of UL 2601-1:10-24-97

Supplementary Information
Included are the following accessories and interconnecting cables:

QUIK-COMBO™ pacing/ defibrillation/ ECG electrodes	Internal handles with discharge controls
QUIK-COMBO PEDIATRIC pacing/ defibrillation/ECG electrodes	Serial cable (system connector)
QUIK-COMBO RTS pacing/ defibrillation/ECG electrodes	FAST-PATCH defibrillation cable
QUIK-COMBO pacing/defibrillation/ ECG electrodes with REDI-PAK™ preconnect system	3-lead ECG cable, 5-lead cable
FAST-PATCH® pacing/defibrillation/ ECG electrodes	QUIK-COMBO defibrillation cable
FAST-PATCH PLUS pacing/ defibrillation/ECG electrodes	SpO2 cable PC04 (4 feet), PC08 (8 feet), PC12 (12 feet)
Standard paddles with built in pediatric paddles (two required)	SpO2 sensor, hard shell, finger (adult and pediatric)
External sterilizable paddles	SpO2 Disposable sensors (Masimo® compatible) (adult and pediatric)
Posterior paddles	SpO2 Option
	External Pacing Option
	Docking Station
	QUIK-COMBO Test Plug

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applies to CE marked devices produced after the date of issuance of this declaration and before it is either superseded by another declaration or withdrawn.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