OPIS

CE 0123

DECLARATION OF CONFORMITY

Manufacturer's Name:	Philips Medical Systems
Manufacturer's Address:	3000 Minuteman Road Andover, Massachusetts 01810-1099 United States

Declares, that the product

Model/Product Name:	SureSigns VM Series Patient Monitors
Starting w/Serial Number:	US61101000

Product Options/Accessories:

M4555A	Antimicrobial non-invasive blood pressure cuff
M1598B	Non-invasive blood pressure interconnect hose
M1191AL	Reusable SpO2 Sensor
989803143381	Temperature probe
M4823A	Temperature probe cover
989803143171	ECG Lead Set
989803136891	Recorder paper

to which this declaration relates is in conformity with Annex I Essential Requirements of the Council Directive: 93/42/EEC
"Council Directive of 14 June 1993 on the approximation of the laws of the Member States concerning medical devices" (Medical Device Directive)

The Manufacturer is certified by TÜV – Product Services GmbH to EN ISO 13485 and Annex II-Section 3.2 of Directive 93/42/EEC. The Quality System certificates are available at http://www3.medical.philips.com/resources/hsg/docs/en-us/custom/intlQualSystemCert_generic.asp

The product is Class IIb according to Annex IX, Rule 10 of Directive 93/42/EEC. Global Medical Device Nomenclature Code (GMDN) is 33586 (Patient monitor, multi-purpose).

Supplementary Information:
The product was tested in a typical configuration as described in the Manufacturer's accompanying documents.

Safety, Performance:	EN 60601-1:1990
ECG monitoring	EN 60601-2-27:1995
NBP monitoring	EN 60601-2-30:2000
IBP monitoring	EN 60601-2-34:2000
SpO_2 monitoring	EN ISO 9919:2005
Predictive Temperature	EN 12470-3:2000
Continuous temperature	EN 12470-4:2000
CO_2 monitoring	EN ISO 21647:2004
Multi-parameter	EN 60601-2-49: 2001
EMC:	EN 60601-1-2: 2001 CISPR 11:1997 +A1: 1999, modified (EN 55011:1998, +A1: 1999)

COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
October 10, 2008

Note: Many of the accessories associated with these devices are independently CE-marked by their manufacturer; compliance with the directive is inclusive of these devices, see manufacturer Declaration of Conformity for additional information.

Andover, 15 March 2006

David R. Jones, WW Quality and Regulatory Manager
PM-Cardiac and Monitoring Systems
Philips Medical Systems

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