

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)

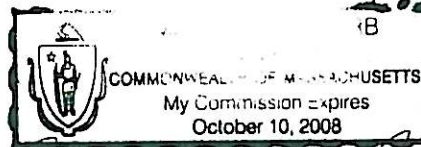
The Manufacturer is certified by TÜV – Product Services GmbH to EN ISO 13485 and Annex II-Section 3.2 of Directive
 93/42/EEC. The Quality System certificates are available at http://www3.medical.philips.com/resources/hsg/docs/en-us/custom/intlQualSystemCert_generic.asp

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)	



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

Authorized EU-representative: Philips Medizin Systeme Böblingen GmbH, Hewlett-Packard Str. 2, 71034 Böblingen, Germany

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