

EC DECLARATION OF CONFORMITY

PHILIPS

Philips Medizin Systeme
Böblingen GmbH
Hewlett-Packard-Str. 2
71034 Böblingen
Germany

This declaration of conformity is issued under the sole responsibility of the manufacturer.

Product Name:	IntelliVue Patient Monitor MP5	<i>excluding the options:</i>	IntelliVue Patient Monitor MP5SC	<i>excluding the options:</i>
Product Model Number or Designator:	M8105A	B11, B14, B21, B24, B31, B41, B44, B54	M8105AS	B11, B14, B16
Product Name:	IntelliVue Patient Monitor MX100	IntelliVue Patient Monitor MX400	IntelliVue Patient Monitor MX430	IntelliVue Patient Monitor MX450
Product Model Number or Designator:	867033	866060	866061	866062
Product Name:	IntelliVue Patient Monitor MX500	IntelliVue Patient Monitor MX550	IntelliVue Patient Monitor MX700	IntelliVue Patient Monitor MX800
Product Model Number or Designator:	866064	866066	865241	865240
Product Name:	IntelliVue Patient Monitor MX750	IntelliVue Patient Monitor MX850	IntelliVue Active Display AD75	IntelliVue Active Display AD85
Product Model Number or Designator:	866471	866470	867130	867133
Product Name:	IntelliVue Multi-Measurement Module X3	Flexible Module Server FMS-8	Flexible Module Server FMS-4	Flexible Module Server FMX-4
Product Model Number or Designator:	867030	M8048A (862461)	865243	866468
Product Name:	Remote Alarm Device	IntelliVue Remote Control	Thermal Array Recorder Module	IntelliVue Dock
Product Model Number or Designator:	866406	865244	M1116C (866336)	867043
Product Name:	IntelliVue MMX	IntelliVue Hemodynamic Extension	IntelliVue Capnography Extension	IntelliVue Microstream Extension
Product Model Number or Designator:	867036	867039	867040	867041
Product Name:	Invasive Blood Pressure Module	Invasive Pressure Module	Cardiac Output Parameter Module	IntelliVue Spirometry Module
Product Model Number or Designator:	M1006B (862277)	M1011A (865124)	M1012A (862279)	M1014A (865021)
Product Name:	IntelliBridge EC10 Module with IntelliBridge EC5 ID-Module	IntelliVue NMT Module with NMT Patient Cable	IntelliVue Pulse Oximetry Module	IntelliVue EEG Module
Product Model Number or Designator:	865115 with 865114	865383 with 989803174581	M1020B (862112)	M1027B (866078)

Product Name:	Temperature Parameter Module	IntelliVue BIS Module	IntelliVue G7m Anesthesia Gas Module with Water Trap
Product Model Number or Designator:	M1029A (862291)	M1034B (866421)	866173 with 989803191081

Product Name:	O3 Module	CO2 Module
Product Model Number or Designator:	867184	867185

Control Indicator: SW Revision M.0x: IntelliVue Patient Monitor MX430.
SW Revision N.0x: IntelliVue Patient Monitors MP5, MP5SC, MX100, MX400, MX450, MX500, MX550, MX700, MX750, MX800, MX850, AD75, AD85 and Multi-Measurement Module X3.
Starting Serial Number: O3 Module 867184: DE682O1001,
Starting Serial Number: CO2 Module 867185: DE683O1001.

Device Classification per specified directive: Class IIb, Rule 10, except for: 865383 with 989803174581 (Class IIa, Rule 10), M1034B (Class IIa, Rule 10), 866173 with 989803191081 (Class IIa, Rule 5).

Global Medical Device Nomenclature Code (GMDN) and Title:

36872 (M8105A, M8105AS, 867033, 866060, 866061, 866062, 866064, 866066, 867030) – Transportable physiologic monitoring system

33586 (865241, 865240, 866470, 866471, 867130, 867133) - Single-patient physiologic monitoring system

36757 (M8048A, 865243, 866468) - Patient monitoring system module rack

36553 (867036, 867030, 867039, 867040, 867041) – Patient monitoring system module, multifunction

36554 (M1020B) – Patient monitoring system module, pulse oximetry

36550 (M1006B) - Patient monitoring system module, blood pressure, invasive

15200 (M1011A) - Intracardiac oximeter

36561 (M1012A) - Patient monitoring system module, cardiac output

35353 (M1014A) - Monitoring spirometer, electrical

37323 (M1027B) - Patient monitoring system module, electroencephalographic

36562 (M1029A) - Patient monitoring system module, temperature

36862 (M1034B, 865115, 865114, 867184, 867185) - Patient monitoring system module, interfacing

35722 (865383, 989803174581) - Block-monitoring peripheral nerve electrical stimulation system

36585 (M1116C) - Patient monitoring system module, printing

37061 (866173) - Patient monitoring system module, multiple-gas

31286 (989803191081) - Breathing circuit condensate trap, reusable

36545 (867043) - Basic power supply

62164 (865244) - Patient monitor remote control

62911 (866406) - Physiologic monitoring system alarm

Product Options/Accessories: All, except patient connected accessories.

The object of the declaration described above is in conformity with:

- **Council Directive 93/42/EEC, Annex II excluding (4) - Section 3.2 concerning medical devices as amended by 2007/47/EC**

EC Certificate information: The Manufacturer is certified by the Notified Body listed below to EN ISO 13485 and Annex II excluding (4) - Section 3.2 of the Medical Device Directive.

Name, Address, and Identification Numbers of Notified Body: TÜV SÜD Product Service GmbH
Ridlerstrasse 65, 80339 München, Germany
ID No.: 0123

Additional Information:

The products listed above have been tested in a typical configuration as described in the Manufacturer's accompanying documentation, and are fully compliant with the standards listed below and other related standards. Additionally, the products listed above have been designed, manufactured, tested, and found to be compatible with the devices and accessories described by the manufacturer in the devices accompanying documentation.

EN 60601-1:2006 + AC:2010 + A1:2013 / IEC 60601-1 Ed.3.1 (cons.) : 2012-08

EN 60601-1-2:2015 / IEC 60601-1-2:2014

Signature (signed for and on behalf of Philips):



Printed Name: Hauke Schik

Title: Director Quality & Regulatory Affairs

Date of Issue: 09-10-2019

Expiration Date: 09-10-2021

Place of Issue: Böblingen