



Declaration of Conformity

Date: 21 July 2014

Manufacturer/Place of Declaration:	Nonin Medical, Inc.	
Address:	13700 1 st Avenue North	
	Plymouth, MN 55441-5443 USA	

Model Numbers and Product Designations: See pages 2 and 3

We herewith declare that the accessories on pages 2 and 3 are classified as Class I (using rule 1) and complies with Annex II, section 3 of the Directive No. 93/42/EEC on medical devices, as amended (2007/47/EC), Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment, (RoHS)

This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

Signature: Name: Title:

Kim J. Que-

Kim E. Aves Senior Regulatory Affairs Specialist



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Model No.

Description

2500 B PalmSAT® Battery 2500C PalmSAT[®] Charger 3150WB Wrist Band reusable 8500P Printer Carbon Dioxide Sensor 9840SA 984AAT Airway Adapt Tube Avant® B Battery Pack 7.2V NiMH Avant[®] Printer Portable Thermal Printer **DAC Module** Digital to Analog Converter Simple cuff - Large Large, blood pressure cuff Simple cuff - Small Small, blood pressure cuff Simple cuff - Standard Standard, blood pressure cuff Cuff-RE-Sm-Ea Small, blood pressure cuff Cuff-RE-Std-Ea Standard, blood pressure cuff Cuff-RE-Lg-Ea Large, blood pressure cuff Cuff-RE-XL-Ea Extra Large, blood pressure cuff Cuff-RE-Sm-5pk Small, blood pressure cuff Cuff-RE-Std-5pk Standard, blood pressure cuff Cuff-RE-Lg-5pk Large, blood pressure cuff Cuff-RE-XL-5pk Extra Large, blood pressure cuff Small, blood pressure cuff Cuff-DIS-Sm-20pk Standard, blood pressure cuff Cuff-DIS-Std-20pk Cuff-DIS-Lg-20pk Large, blood pressure cuff Extra Large, blood pressure cuff Cuff-DIS-XL-20pk Tub-ST-Ea Straight hose from 2120 to BP cuff Coiled hose from 2120 to BP cuff Tub-CO-Fa 8000JFW FlexiWrap[™], Adult 8001JFW FlexiWrap[™], Infant FlexiWrap[™], Neonate 8008JFW Serial Cable, Memory for 2500, 1000MC 8500 and 9840 series 1000PFC Patient Interface Cable, Memory Or Real-Time, for 8600 series 1000RTC Serial Cable, Memory or Real-Time, 2500, 8500 and 9840 series 1000SC-WO PC Interface Cable - WristOx® 31001 Sensor Adapter Cable for WristOx, 7 inch / 0.18 meter cable 31501 Sensor Adapter Cable for WristOx2 3150SC Serial Cable 7500SC 7500 Serial Output Cable Analog Cable w/Tinned Leads, 9ft/3m 8604E 8604E-J Analog Cable w/Banana Jacks, 9ft/3m 88001 Patient Interface Cable, 9 ft/3m Nurse Call Output, 2m w/ ¼" plug 9600 NC-6 Nurse Call Output, 3m w/ ¼" plug 9600 NC-10 Nurse Call Output, 3m w/o plug 9600 NC-10x Extension Cable, 3 ft / 1 m cable UNI-EXT-1 UNI-EXT-3 Extension Cable, 10 ft / 3 m cable UNI-EXT-6 Extension Cable, 20 ft / 6 m cable Extension Cable, 30 ft / 9 m cable UNI-EXT-9 UNI-RA-0 Right Angle Connector, 6 in/0.15 m Right Angle Connector, 10 ft/3 m UNI-RA-3

Date Added

October 2000 October 2000 September 2010 August 1995 March 2002 March 2002 November 2002 June 2003 September 2003 March 2002 March 2002 March 2002 May 2007 March 1999 March 1999 March 1999 December 2001 December 2001 December 2001 December 2001 December 2001 September 2010 September 2010 May 2007 December 2001 December 2001

GMDN

40374, Battery, rechargeable 17115, Battery charger 36585, Patient monitoring system module, printing

37428, Connector 34158, Battery, secondary 36585, Patient monitoring system module, printing

34978, Cuff, blood pressure, reusable 37326, Cuff, blood pressure, single-use 10026, Adhesive Strips 10026, Adhesive Strips 10026, Adhesive Strips



ENONÍN



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Model No.	Description	Date Added	GMDN
UNI-RS232	Download Cable for Avant [®] Products	December 2001	
Avant [®] DAC	Digital to Analog Converter	December 2001	
Avant [®] DAC Kit	Digital to Analog Converter ¹	December 2001	
nVision®	Data Management Software	March 2001	17762, Data Management Software
	for Oximetry		
300PS-UNIV	Power Supply–Universal (w/o cord)	August 1995	36545, Power Supply, general purpose
301PS-UNIV	Power Supply–Universal (w/o cord)	August 1995	36545, Power Supply, general purpose
302PS-UNIV	Power Supply–Universal (w/o cord)	August 1995	36545, Power Supply, general purpose
8000A	Power Supply, Euro Wall, 230VAC-8VDC	December 2004	36545, Power Supply, general purpose
1300PC-EU	Power Cord, Continental Europe	July 1999	36529, Power Supply
	(Schuko) CEE7 Medical-grade		
RS-S	Standard 5-point rolling stand	January 2002	40596, Trolley, electromechanical device
	w/adjustable pole height		
Go2 Lanyard	Lanyard	May 2009	
GO2 Retractable	Lanyard, retractable	May 2009	
Lanyard			
GO2 Carrying Case	Carrying Case	May 2009	11836, Medical Device Carriers
Moisture Trap	Moisture Trap with Filters	July 2010	15608, Traps; 11710, filters

¹ Includes RS232 and audio cable