

Declaration of Conformity


Date: 12 December, 2017

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

Model Numbers and Product Designations: See pages 2, 3 and 4

We herewith declare that the accessories on pages 2 and 3 are classified as Class I (using rule 1) and comply with Annex II, section 3 of the Directive No. 93/42/EEC on medical devices, as amended (2007/47/EC).

This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

Signature: 
Name: Kim E. Aves
Title: Principal Regulatory Affairs Specialist

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Model No.	Description	Date Added	GMDN
2500B	Battery Pack, 2500	October 2000	40374, Battery, rechargeable
2500C	PalmsAT® Charger	October 2000	17115, Battery charger
3150WB	Wrist Band reusable	September 2010	
9840SA	Carbon Dioxide Sensor	March 2002	
984AAT	Airway Adapt Tube	March 2002	37428, Connector
9863-001	Battery Pack (7.2V NiMH)	October 2014	40374, Battery, rechargeable
9862-001	Battery Pack (4.8V NiMH)	October 2014	40374, Battery, rechargeable
9862-002	Battery Pack (4.8V NiMH)	October 2014	40374, Battery, rechargeable
DAC Module	Digital to Analog Converter	September 2003	
Cuff-RE-Sm-Ea	Small, blood pressure cuff	May 2007	34978, Cuff, blood pressure, reusable
Cuff-RE-Std-Ea	Standard, blood pressure cuff	May 2007	34978, Cuff, blood pressure, reusable
Cuff-RE-Lg-Ea	Large, blood pressure cuff	May 2007	34978, Cuff, blood pressure, reusable
Cuff-RE-XL-Ea	Extra Large, blood pressure cuff	May 2007	34978, Cuff, blood pressure, reusable
Tub-ST-Ea	Straight hose from 2120 to BP cuff	May 2007	37326, Cuff, blood pressure, single-use
Tub-CO-Ea	Coiled hose from 2120 to BP cuff	May 2007	37326, Cuff, blood pressure, single-use
8000JFW	FlexiWrap™, Adult	March 1999	10026, Adhesive Strips
8001JFW	FlexiWrap™, Infant	March 1999	10026, Adhesive Strips
8008JFW	FlexiWrap™, Neonate	March 1999	10026, Adhesive Strips
1000MC	Serial Cable, Memory for 2500, 8500 and 9840 series	December 2001	37096, Cable
1000PFC	Patient Interface Cable, Memory Or Real-Time, for 8600 series	December 2001	37096, Cable
1000RTC	Serial Cable, Memory or Real-Time, 2500, 8500 and 9840 series	December 2001	37096, Cable
1000SC-WO	PC Interface Cable - WristOx®	December 2001	37096, Cable
3100I	Sensor Adapter Cable for WristOx, 7 inch / 0.18 meter cable	December 2001	37096, Cable
3150I	Sensor Adapter Cable for WristOx2	September 2010	37096, Cable
3150SC	Serial Cable	September 2010	37096, Cable
7500SC	7500 Serial Output Cable	May 2007	37096, Cable
8604E	Analog Cable w/Tinned Leads, 9ft/3m	December 2001	37096, Cable
8604E-J	Analog Cable w/Banana Jacks, 9ft/3m	December 2001	37096, Cable
8800I	Patient Interface Cable, 9 ft/3m	December 2001	37096, Cable
9600 NC-6	Nurse Call Output, 2m w/ ¼" plug	December 2001	37096, Cable
9600 NC-10	Nurse Call Output, 3m w/ ¼" plug	December 2001	37096, Cable
9600 NC-10x	Nurse Call Output, 3m w/o plug	December 2001	37096, Cable
UNI-EXT-1	Extension Cable, 3 ft / 1 m cable	December 2001	37096, Cable
UNI-EXT-3	Extension Cable, 10 ft / 3 m cable	December 2001	37096, Cable
UNI-EXT-6	Extension Cable, 20 ft / 6 m cable	December 2001	37096, Cable
UNI-EXT-9	Extension Cable, 30 ft / 9 m cable	December 2001	37096, Cable

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Model No.	Description	Date Added	GMDN
UNI-RA-3	Right Angle Connector, 10 ft/3 m	December 2001	37096, Cable
UNI-RS232	Download Cable for Avant® Products	December 2001	37096, Cable
Avant® DAC	Digital to Analog Converter	December 2001	
Avant® DAC Kit	Digital to Analog Converter ¹	December 2001	
Avant® RS-D	5-point rolling stand	January 2002	40596, Trolley, electromechanical device
Avant® CC	Carrying Case, Avant Series (2120,4000, 9600, 9700)	February, 2002	11836, Medical Device Carriers
nVision®	Data Management Software for Oximetry	March 2001	17762, Data Management Software
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
MPP30M-002	Power Supply–Universal (w/o cord)	December 2012	36545, Power Supply, general purpose
MPP30M-003	Power Supply–Universal (w/o cord)	December 2012	36545, Power Supply, general purpose
MPP30M-004	Power Supply–Universal (w/o cord)	December 2012	36545, Power Supply, general purpose
MPP30M-005	Power Supply–Universal (w/o cord)	December 2012	36545, Power Supply, general purpose
7801PS	US Power Cord		
7802PS	OUS Power Cord		
Plug Kit	International Power Supply Plug Kit		
7600PCS-US	Power Cord		
7600PCS-Australia	Power Cord		
7600PCS-UK	Power Cord		
7600PCS-EU	Power Cord		
Plug Set	Australia International Power Supply Plug Kit		
Plug Set	UK International Power Supply Plug Kit		
Plug Set	EU/Brazil International Power Supply Plug Kit		
Plug Set	Americas/Japan International Power Supply Plug Kit		
1300PC-EU	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-AR	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-DEN	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-India/SA	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose

¹ Includes RS232 and audio cable

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Model No.	Description	Date Added	GMDN
1300PC-IL	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-IT	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-UK	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-AU	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-CN	Battery Charger Cordset	December 2004	36545, Power Supply, general purpose
1300PC-USA	Battery Charger Cordset	December 2004	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 (Schuko) CEE7 Medical-grade	July 1999	36545, Power Supply, general purpose
GO2 Lanyard	Lanyard	May 2009	
GO2 Retractable Lanyard	Lanyard, retractable	May 2009	
GO2CC	G02 Carrying Case	May 2009	11836, Medical Device Carriers
9500CC	Fingertip Carrying Case	May 2009	11836, Medical Device Carriers
8500RB	Rubber Bumper	August 1995	
3150WI	Interface Adaptor Cable		42410, Cable Lead Holder
8000H	Reflectance Sensor Holder		43266, Sensor Holder