

Declaration of Conformity

Date: 21 July 2014

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

Model Numbers and Product Designations: See page 2

Device Category(ies): Probe, oximeter, reusable;
Probe, pulse oximeter, single-use

GMDN Number(s): 37808, 31658

Date Added: See page 2

We herewith declare that the pulse oximeter sensors listed on the accompanying pages are classified as Class IIb (using rule 10) 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) and all applicable clauses of ISO 80601-2-61:2011,, *Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.*

This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstrasse 65
D-80339 München
Germany

EC Certificate Number: G1 13 09 24497 023

Number CE0123

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

Authorized EC Representative:
Medical Product Service (MPS) GmbH
Borngasse 20
35619 Braunfels
Germany



Model No.	Product Description	Date Added
Reusable Sensor Product Listing		
8000AA	Adult Articulated Internal Spring Finger Clip, 3ft/1m cable	AUG 1995
8000AA-2	Adult Articulated Internal Spring Finger Clip, 6ft/2m cable	AUG 1995
8000AA-3	Adult Articulated Internal Spring Finger Clip, 9ft/3m cable	AUG 1995
8000AA-WO	Adult Articulated Finger Clip – WristOx®, 1ft/.3m cable	AUG 1995
8000AP	Pediatric External Spring Finger Clip, 3ft/1mcable	AUG 1995
8000AP-3	Pediatric External Spring Finger Clip, 9ft/3b cable	AUG 1995
8000FC-20	Adult/Pediatric Fiber Optic, 20 foot cable ¹	AUG 1995
8000FC-30	Adult/Pediatric Fiber Optic, 30 foot cable ⁵	AUG 1995
8000FI-20	Infant/Pediatric Fiber Optic, 20 foot cable ²	AUG 1995
8000FI-30	Infant/Pediatric Fiber Optic, 30 foot cable ⁶	AUG 1995
8000J	Adult Flex, 3 feet / 1 meter cable ³	AUG 1995
8000J-3	Adult Flex, 3 feet / 1 meter cable ¹	AUG 1995
8000J-WO	Adult Flex – WristOx®, 12 inch / 0.3 meter cable ¹	AUG 1995
8001J	Neonatal Flex, 3 feet / 1 meter cable ⁴	AUG 1995
8008J	Infant Flex, 3 feet / 1 meter cable ⁵	AUG 1995
8000Q2	Ear Clip, 3 feet / 1 meter cable	MAY2008
8000R	Reflectance, 3 feet / 1 meter cable ⁶	AUG 1995
8000SS	Sensor, Reusable, Soft, Small, 1 Meter	JUN 2006
8000SM	Sensor, Reusable, Soft, Medium, 1 Meter	JUN 2006
8000SL	Sensor, Reusable, Soft, Large, 1 Meter	JUN 2006
8000SS-3	Sensor, Reusable, Soft, Small, 3 Meter	JUN 2006
8000SM-3	Sensor, Reusable, Soft, Medium, 3 Meter	JUN 2006
8000SL-3	Sensor, Reusable, Soft, Large, 3 Meter	JUN 2006
8000SS-WO	Sensor, Reusable, Soft, Small, 1 Meter	JUN 2006
8000SM-WO	Sensor, Reusable, Soft, Medium, 1 Meter	JUN 2006
8000SL-WO	Sensor, Reusable, Soft, Large, 1 Meter	JUN 2006
8000AA-WO2	Adult Articulated Internal Spring Finger Clip, 3ft/1m cable	DEC 2010
8000J-WO2	Adult Flex, 3 feet / 1 meter cable ⁷	DEC 2010
8000SS-WO2	Sensor, Reusable, Soft, Small, 1 Meter	DEC 2010
8000SM-WO2	Sensor, Reusable, Soft, Medium, 1 Meter	DEC 2010
8000SL-WO2	Sensor, Reusable, Soft, Large, 1 Meter	DEC 2010
8100SS	Sensor, Reusable, Soft, Small, X-100 System	MAY 2013
8100SM	Sensor, Reusable, Soft, Small, X-100 System	MAY 2013
8100SL	Sensor, Reusable, Soft, Small, X-100 System	MAY 2013
Disposable Sensor Product Listing		
7000A	Flexi-Form® III Adult, 3 feet/11 meter	AUG 1995
7000P	Flexi-Form® III Pediatric, 3 feet/1 meter cable	AUG 1995
7000I	Flexi-Form® III Infant, 3 feet / 11 meter	AUG 1995
7000N	Flexi-Form® III Neonate, 3 feet / 11 meter	AUG 1995
6000CA	Sensor, Disposable, Adult, 45cm Cable	JUN 2010
6000CP	Sensor, Disposable, Pediatric, 45cm Cable	JUN 2010
6000CI	Sensor, Disposable, Infant, 90cm Cable	JUN 2010
6000CN	Sensor, Disposable, Neonate, 90cm Cable	JUN 2010
6500MA	Sensor, Disposable, Adult	OCT 2010
6500SA	Sensor, Disposable, Adult	OCT 2010

¹ Includes 8000FW, Fiber Optic Finger Wrap 2-pack

² Includes 8000TW, Fiber Optic Toe Wrap 2-pack

³ Includes 25 FlexiWrap® Adult 8000JFW

⁴ Includes 25 8001 JFW FlexiWrap® Neonatal

⁵ Includes 25 8008JFW FlexiWrap® Infant

⁶ Includes 8000H Reflectance Sensor Holder, (10 caps & 20 Adhesive Stickers)

⁷ Includes 25 FlexiWrap® Adult 8000JFW