

Declaration of Conformity

Date: 21 December 2018

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), 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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 024497 0030 Rev. 00

Number CE0123

Signature:



Name:

Kim E. Aves

Title:

Principal Regulatory Affairs Specialist

Authorized EC Representative:

Medical Product Service (MPS) GmbH
Borngasse 20
35619 Braunfels
Germany

Sensor Declaration of Conformity
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Model No ¹	Product Description	Date Added	Country of Manufacture ²
Reusable Sensor Product Listing			
8000AA	Adult Articulated Finger Clip, 3ft /1 m cable	AUG 1995	CN
8000AA-2	Adult Articulated Finger Clip, 6ft/2 m cable	AUG 1995	CN
8000AA-3	Adult Articulated Finger Clip, 9ft/3 m cable	AUG 1995	CN
8000AA-WO	Adult Articulated Finger Clip – WristOx®, 1ft/.3m cable	AUG 1995	CN
8000AP	Pediatric Finger Clip, 3ft/1m cable	AUG 1995	CN
8000AP-2M	Pediatric Finger Clip, 6ft/2 m cable	AUG 1995	CN
8000AP-3M	Pediatric Finger Clip, 9ft/3m cable	AUG 1995	CN
8000FC-20	Adult/Pediatric Fiber Optic, 20 foot cable ³	AUG 1995	US
8000FC-30	Adult/Pediatric Fiber Optic, 30 foot cable ⁵	AUG 1995	US
8000FI-20	Infant/Pediatric Fiber Optic, 20 foot cable ⁴	AUG 1995	US
8000FI-30	Infant/Pediatric Fiber Optic, 30 foot cable ⁶	AUG 1995	US
8000J	Adult Flex, 3 feet / 1 meter cable ⁵	AUG 1995	US
8000J-3	Adult Flex, 9 feet / 3 meter cable ¹	AUG 1995	US
8000J-WO	Adult Flex – WristOx®, 12 inch / 0.3 meter cable ¹	AUG 1995	US
8001J	Neonatal Flex, 3 feet / 1 meter cable ⁶	AUG 1995	US
8008J	Infant Flex, 3 feet / 1 meter cable ⁷	AUG 1995	US
8000Q2	Ear Clip, 3 feet / 1 meter cable	MAY2008	US
8000R	Reflectance, 3 feet / 1 meter cable ⁸	AUG 1995	US
8000SS	Soft Sensor, Reusable, Small, 1 Meter	JUN 2006	CN
8000SM	Soft Sensor, Reusable, Medium, 1 Meter	JUN 2006	CN
8000SL	Soft Sensor, Reusable, Large, 1 Meter	JUN 2006	CN
8000SS-3	Soft Sensor, Reusable, Small, 3 Meter	JUN 2006	CN
8000SM-3	Soft Sensor, Reusable, Medium, 3 Meter	JUN 2006	CN
8000SL-3	Soft Sensor, Reusable, Large, 3 Meter	JUN 2006	CN
8000SS-WO	Soft Sensor, Reusable, Small, 1 Meter	JUN 2006	CN
8000SM-WO	Soft Sensor, Reusable, Medium, 1 Meter	JUN 2006	CN
8000SL-WO	Soft Sensor, Reusable, Large, 1 Meter	JUN 2006	CN
8000AA-WO2	Adult Articulated Finger Clip, 3ft/1m cable	DEC 2010	CN
8000J-WO2	Adult Flex, 3 feet / 1 meter cable ⁹	DEC 2010	CN
8000SS-WO2	Soft Sensor, Reusable, Small, 1 Meter	DEC 2010	CN
8000SM-WO2	Soft Sensor, Reusable, Medium, 1 Meter	DEC 2010	CN
8000SL-WO2	Soft Sensor, Reusable, Large, 1 Meter	DEC 2010	CN

¹ All Nonin-branded pulse oximeter sensors listed on this declaration are designed and developed by Nonin Medical, Inc., a company located in the United States
² Country of manufacture, other than US is the location of the contract manufacturer, producing per Nonin Medical specifications; country codes are ISO Alpha-2 format.
³ Includes 8000FW, Fiber Optic Finger Wrap 2-pack
⁴ Includes 8000TW, Fiber Optic Toe Wrap 2-pack
⁵ Includes 25 FlexiWrap® Adult 8000JFW
⁶ Includes 25 8001 JFW FlexiWrap® Neonatal
⁷ Includes 25 8008JFW FlexiWrap® Infant
⁸ Includes 8000H Reflectance Sensor Holder, (10 caps & 20 Adhesive Stickers)
⁹ Includes 25 FlexiWrap® Adult 8000JFW



Model No¹⁰.	Product Description	Date Added	Country of Manufacture¹¹
Disposable Sensor Product Listing			
7000A	Flexi-Form [®] III Adult, 3 feet/11 meter	AUG 1995	CN
7000P	Flexi-Form [®] III Pediatric, 3 feet/1 meter cable	AUG 1995	CN
7000I	Flexi-Form [®] III Infant, 3 feet/1 meter	AUG 1995	CN
7000N	Flexi-Form [®] III Neonate, 3 feet/1 meter	AUG 1995	CN
6000CA	Sensor, Disposable, Adult, 45cm Cable	JUN 2010	CN
6000CP	Sensor, Disposable, Pediatric, 45cm Cable	JUN 2010	CN
6000CI	Sensor, Disposable, Infant, 90cm Cable	JUN 2010	CN
6000CN	Sensor, Disposable, Neonate, 90cm Cable	JUN 2010	CN
6500MA	Sensor, Durafoam Disposable, Adult	OCT 2010	US
6500SA	Sensor, Durafoam Disposable, Adult	OCT 2010	US

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¹¹ Country of manufacture, other than US is the location of the contract manufacturer, producing per Nonin Medical specifications; country codes are ISO Alpha-2 format.

We certify that products listed below are designed and developed by and produced to Nonin Medical specifications through contract manufacturing by Measurement Specialties, Inc., in Shenzhen, China, and shipped by and from Nonin Medical, Plymouth, MN, USA.

Model 6000CA, Cloth Disposable Sensor, Adult
Model 6000CP, Cloth Disposable Sensor, Pediatric
Model 6000CI, Cloth Disposable Sensor, Infant
Model 6000CN, Cloth Disposable Sensor, Neonate
Model 7000A, Disposable Sensor, Adult
Model 7000P, Disposable Sensor, Pediatric
Model 7000I, Disposable Sensor, Infant
Model 7000N, Disposable Sensor, Neonate
Model 8000AA, Adult Articulated Pulse Oximeter Finger Clip Sensor
Model 8000AP, Pediatric Articulated Pulse Oximeter Finger Clip Sensor
Model 8000AA-WO, Adult Articulated Pulse Oximeter Finger Clip Sensor
Model 8000SS, Soft Sensor, Small
Model 8000SM, Soft Sensor, Medium
Model 8000SL, Soft Sensor, Large
Model 8000SS-WO, Reusable Soft Sensor, Small
Model 8000SM-WO, Reusable Soft Sensor, Medium,
Model 8000SL-WO, Reusable Soft Sensor, Large,
Model 8000SS-WO2, Reusable Soft Sensor, Small,
Model 8000SM-WO2, Reusable Soft Sensor, Medium,
Model 8000SL-WO2, Reusable Soft Sensor, Large,

Nonin Medical, Inc. certifies that products listed below are manufactured by Nonin Medical, Inc., Plymouth, MN, and shipped from Nonin Medical, Plymouth, MN, USA.

Model 6500MA, Durable Disposable Sensor, Adult
Model 6500SA, Durable Disposable Sensor, Adult
Model 8000J, Flex Sensor, Adult
Model 8001J, Flex Sensor, Neonatal
Model 8008J, Flex Sensor, Infant
Model 8000J-WO2, Flex Sensor, Adult
Model 8000Q2, Ear Clip Sensor
Model 8000R, Reflectance Sensor
Model 8000FC, Fiber Optic Sensor, Adult/Pediatric
Model 8000FI, Fiber Optic Sensor, Infant/Pediatric

The following Sensor Accessories are manufactured in the United States:

Model 8000JFW, Adult FlexiWrap
Model 8001JFW, Neonate FlexiWrap
Model 8008JFW, Infant FlexiWrap