

Declaration of Conformity

Date: 14 January 2019

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 80601-2-61:2017, *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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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

Page 2

| 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 No ¹⁰ | Product Description | Date Added | Country of Manufacture ¹¹ |
|--|---|------------|--------------------------------------|
| Disposable Sensor Product Listing | | | |
| 7000A | Flexi-Form® III Adult, 3 feet/11 meter | AUG 1995 | IN |
| 7000P | Flexi-Form® III Pediatric, 3 feet/1 meter cable | AUG 1995 | IN |
| 7000I | Flexi-Form® III Infant, 3 feet/1 meter | AUG 1995 | IN |
| 7000N | Flexi-Form® III Neonate, 3 feet/1 meter | AUG 1995 | IN |
| 6000CA | Sensor, Disposable, Adult, 45cm Cable | JUN 2010 | IN |
| 6000CP | Sensor, Disposable, Pediatric, 45cm Cable | JUN 2010 | IN |
| 6000CI | Sensor, Disposable, Infant, 90cm Cable | JUN 2010 | IN |
| 6000CN | Sensor, Disposable, Neonate, 90cm Cable | JUN 2010 | IN |
| 6500MA | Sensor, Durafoam Disposable, Adult | OCT 2010 | US |
| 6500SA | Sensor, Durafoam Disposable, Adult | OCT 2010 | US |

¹⁰ 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

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.