

## Declaration of Conformity

**Date:** 14 January 2019

**Manufacturer/Place of Declaration:** Nonin Medical, Inc.  
**Address:** 13700 1<sup>st</sup> 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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  
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Sensor Declaration of Conformity

Page 2

| Model No <sup>1</sup>                  | Product Description   | Date Added | Country of Manufacture <sup>2</sup> |
|--|---|------------|-------------------------------------|
| <b>Reusable Sensor Product Listing</b> |   |            |                                     |
| 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 <sup>3</sup>       | AUG 1995   | US                                  |
| 8000FC-30                              | Adult/Pediatric Fiber Optic, 30 foot cable <sup>5</sup>       | AUG 1995   | US                                  |
| 8000FI-20                              | Infant/Pediatric Fiber Optic, 20 foot cable <sup>4</sup>      | AUG 1995   | US                                  |
| 8000FI-30                              | Infant/Pediatric Fiber Optic, 30 foot cable <sup>6</sup>      | AUG 1995   | US                                  |
| 8000J                                  | Adult Flex, 3 feet / 1 meter cable <sup>5</sup>               | AUG 1995   | US                                  |
| 8000J-3                                | Adult Flex, 9 feet / 3 meter cable <sup>1</sup>               | AUG 1995   | US                                  |
| 8000J-WO                               | Adult Flex – WristOx®, 12 inch / 0.3 meter cable <sup>1</sup> | AUG 1995   | US                                  |
| 8001J                                  | Neonatal Flex, 3 feet / 1 meter cable <sup>6</sup>            | AUG 1995   | US                                  |
| 8008J                                  | Infant Flex, 3 feet / 1 meter cable <sup>7</sup>              | AUG 1995   | US                                  |
| 8000Q2                                 | Ear Clip, 3 feet / 1 meter cable                              | MAY2008    | US                                  |
| 8000R                                  | Reflectance, 3 feet / 1 meter cable <sup>8</sup>              | 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 <sup>9</sup>               | 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                                  |

<sup>1</sup> 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

<sup>2</sup> 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.

<sup>3</sup> Includes 8000FW, Fiber Optic Finger Wrap 2-pack

<sup>4</sup> Includes 8000TW, Fiber Optic Toe Wrap 2-pack

<sup>5</sup> Includes 25 FlexiWrap® Adult 8000JFW

<sup>6</sup> Includes 25 8001 JFW FlexiWrap® Neonatal

<sup>7</sup> Includes 25 8008JFW FlexiWrap® Infant

<sup>8</sup> Includes 8000H Reflectance Sensor Holder, (10 caps & 20 Adhesive Stickers)

<sup>9</sup> Includes 25 FlexiWrap® Adult 8000JFW

| Model No <sup>10</sup> .                 | Product Description                             | Date Added | Country of Manufacture <sup>11</sup> |
|--|---|------------|--------------------------------------|
| <b>Disposable Sensor Product Listing</b> |   |            |                                      |
| 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                                   |

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