

Declaration of Conformity

Date: 17 November 2008

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

**Model Numbers and
Product Designations:** See pages 2 and 3 of this declaration

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

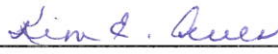
GMDN Number(s): 37808
31658

Date Added: See pages 2 and 3 of this declaration

We herewith declare that the pulse oximeter sensors listed on the accompanying pages are classified as Class IIb (using rule 10) and comply with the EC Directive No. 93/42/EEC.

Notified Body: TÜV Product Service GMBH
Zertifizierstelle
Ridlerstrasse 65
D-80339 München
Germany

EC Certificate Number: G1 05 07 24497 019

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

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

Nonin Medical Inc.
Declaration of Conformity
17 November 2008
Page 2

Reusable Sensor Product Listing

Model Number	Product Designation	Date Added
8000AA	Adult Articulated Internal Spring Finger Clip, 3 feet / 1 meter cable	August 1995
8000AA-2	Adult Articulated Internal Spring Finger Clip, 6 feet / 2 meter cable	August 1995
8000AA-3	Adult Articulated Internal Spring Finger Clip, 9 feet / 3 meter cable	August 1995
8000AA-WO	Adult Articulated Finger Clip – WristOx®, 12 inch / 0.3 meter cable	August 1995
8000AP	Pediatric External Spring Finger Clip, 3 feet / 1 meter cable	August 1995
8000AP-3	Pediatric External Spring Finger Clip, 9 feet / 3 meter cable	August 1995
8000J	Adult Flex, 3 feet / 1 meter cable ¹	August 1995
8000J-3	Adult Flex, 3 feet / 1 meter cable ¹	August 1995
8000J-WO	Adult Flex – WristOx®, 12 inch / 0.3 meter cable ¹	August 1995
8000Q	Ear Clip, 3 feet / 1 meter cable	August 1995
8000Q2	Ear Clip, 3 feet / 1 meter cable	May 2008
8000R	Reflectance, 3 feet / 1 meter cable ²	August 1995
8001J	Neonatal Flex, 3 feet / 1 meter cable ³	August 1995
8008J	Infant Flex, 3 feet / 1 meter cable ⁴	August 1995

¹ Includes 25 FlexiWrap® Adult 8000JFW

² Includes 8000H Reflectance Sensor Holder, 10 caps & 20 Adhesive Stickers)

³ Includes 25 8001 JFW FlexiWrap® Neonatal

⁴ Includes 25 8008JFW FlexiWrap® Infant



Nonin Medical Inc.
Declaration of Conformity
17 November 2008
Page 3

Nonin Medical, Inc.
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USA

Disposable Sensor Product Listing

Model Number	Product Designation	Date Added
7000A	Flexi-Form® II Adult, 3 feet / 11 meter, 10-pack	August 1995
7000P	Flexi-Form® II Pediatric, 3 feet / 1 meter cable, 10-pack	August 1995
7000I	Flexi-Form® II Infant, 3 feet / 11 meter, 10-pack	August 1995
7000N	Flexi-Form® II Adult, 3 feet / 11 meter, 10-pack	August 1995
7000D	Flexi-Form® II Assortment, 3 feet / 11 meter, (4-A, 2-I, 2-N, 2-P), 3 feet / 1 meter cable	August 1995
8000FC-20	Adult/Pediatric Fiber Optic, 20 foot cable ⁵	August 1995
8000FC-30	Adult/Pediatric Fiber Optic, 30 foot cable ⁵	August 1995
8000FI-20	Infant/Pediatric Fiber Optic, 20 foot cable ⁶	August 1995
8000FI-30	Infant/Pediatric Fiber Optic, 30 foot cable ⁶	August 1995

⁵ Includes 8000FW, Fiber Optic Finger Wrap 2-pack

⁶ Includes 8000TW, Fiber Optic Toe Wrap 2-pack