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:	**Date Added**	**GMDN**
Avant 2120, Pulse Oximeter and NIBP Monitor System	03/2002	17148, oximeter, pulse 31681, Patient monitor, blood pressure, noninvasive
2500, 2500A PalmSat® Pulse Oximeter System	03/2002	17148, oximeter, pulse
3100, WristOx® Wearable Pulse Oximeter System	03/2002	17148, oximeter, pulse
Avant® 4000, 4100, Wearable Digital Pulse Oximeter System	03/2004	17148, oximeter, pulse
7500, Digital Pulse Oximeter System	05/2007	17148, oximeter, pulse
7500FO Digital Fiber Optic Pulse Oximeter System	06/2007	17148, oximeter, pulse
7600, Regional Oximeter System	05/2009	17942, oximeter, cerebral
8500, 8500M, Pulse Oximeter Systems	08/1995	17148, oximeter, pulse
9500, Onyx® Finger Tip Pulse Oximeter	08/1995	17148, oximeter, pulse
9550 Onyx® II Finger Tip Pulse Oximeter	06/2005	17148, oximeter, pulse
9560 Onyx® II Finger Tip Pulse Oximeter	05/2008	17148, oximeter, pulse
9570 GO2 Finger Tip Pulse Oximeter	05/2009	17148, oximeter, pulse
9571GO2 LED Finger Tip Pulse Oximeter	11/2009	17148, oximeter, pulse
9590 Onyx® Vantage Finger Pulse Oximeter	09/2011	17148, oximeter, pulse
9600 Avant® Pulse Oximeter System	11/2002	17148, oximeter, pulse
9700 Avant® Pulse Oximeter System with Waveform	10/2003	17148, oximeter, pulse
9843, 9847, Digital Pulse Oximeter & CO_2 Detector System	03/2002	17148, oximeter, pulse 17224, Carbon Dioxide Monitor

We herewith declare that the above mentioned pulse oximeters and systems are classified as Class IIb (using rule 10) and comply 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.*

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

EC Certificate Number: G1 13 09 24497 023

Number CE0123

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

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