Declaration of Conformity

Date: 17 December 2018

Manufacturer/Place of Declaration:	Nonin Medical, Inc.
Address:	13700 1st Avenue North Plymouth, MN 55441-5443 USA
Model Numbers and Product Designations:	3150, 3150SK, 3150BLE, 3150 SK BLE WristOx2® Wrist-Worn Pulse Oximeter with Bluetooth®
Device Category(ies):	Telemetry system, pulse oximetry
GMDN Number(s):	36118
Date Added:	September 2010 (3150, 3150SK); July, 2018 (3150BLE, 3150 SK BLE)

We herewith declare that the above mentioned pulse oximeter is 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, *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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

We further declare, under our sole responsibility, that the above mentioned pulse oximeter to which this declaration relates is in conformity with the following standards and/or other normative documents:

DIRECTIVE 2014/53/EU *OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC*

EN 301 489-17 V3.1.1:2017, *ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems;* Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU[1]

Notified Body:	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München Germany
EC Certificate Number:	G1 024497 0030 Rev.00
Number	CE0123
Signature:	Kim E. Aves
Name:	Kim E. Aves
Title:	Principal Regulatory Affairs Specialist

Authorized EC Representative:
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[1] Element NONN0179, NONN0179.1