

Declaration of Conformity

Date: 22 July 2014

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

Model Numbers and Product Designations: 3150
WristOx2® Wrist-Worn Pulse Oximeter with Bluetooth®

Device Category(ies): Telemetry system, pulse oximetry

GMDN Number(s): 36118

Date Added: September 2010

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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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

1999/5/EC "*Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity*" April 7, 1999

EN 300 328 "*Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonised EN covering essential requirements under Article 3(2) of the R&TTE Directive*" V1.7.1 (2006-10)

EN 55022 *Limits and Methods of Measurement of Radio Interference Characteristics of Information Technology Equipment* 1988.

Notified Body: TÜV SÜD Product Service GmbH
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Germany

EC Certificate Number: G1 13 09 24497 023

Number CE0123

Signature:

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