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:	LS1-9R, LS1P-9R, LS1R-9R Capnometer/Pulse Oximeter System; Pulse Oximeter System; Capnometer System
Device Category(ies):	Oximeter, pulse
GMDN Number(s):	17148
Date Added:	16 July 2010

We herewith declare that the above mentioned pulse oximeter system 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 80601-2-61:2011, *Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use* and ISO 21647:2004 *Medical electrical equipment – Particular requirements for the basic safety and essential performance of respiratory gas monitors.*

This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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 13 09 24497 023
Number	CE0123

Signature: Kim E. Aves

Name: Kim E. Aves

Title: Senior Regulatory Affairs Specialist

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