Declaration of Conformity

Date: 12 January 2016

Manufacturer/Place of Declaration:	Nonin Medical, Inc.
Address:	13700 1st Avenue North Plymouth, MN 55441-5443 USA
Model Numbers and Product Designations:	LifeSense, Model LS1, RespSense, Model LS1R Capnometer/Pulse Oximeter; Capnometer
Device Category(ies):	Capnograph/Pulse Oximeter Capnograph
GMDN Code, Term:	31339, Analyser, Gas, Carbon Dioxide 17148, Pulse Oximeter, line-powered
Date Added:	12 January 2016

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, *Particular requirements for basic safety and essential performance of pulse oximeter equipment* and ISO 80601-2-55:2011, *Particular requirements for 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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

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