

Declaration of Conformity

Date: 01 November 2013

Manufacturer: Nonin Medical, Inc. 13700 1st Avenue North Address:

Plymouth, MN 55441-5443 USA

Model Numbers and LS1-9R, LS1P-9R, LS1R-9R

Product Designations: 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), and all applicable clauses of ISO 9919:2005, 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

TÜV SÜD Product Service GmbH Notified Body:

> Ridlerstrasse 65 D-80339 München

Germany

EC Certificate Number: G1 10 02 24497 023

GMDN: 17148 / 17224

Sim Q. Were Signature:

Name:

Title: Senior Regulatory Affairs Specialist

Authorized EC Representative:

Medical Product Service (MPS) GmbH Borngasse 20 35619 Braunfels Germany