Declaration of Conformity

Date: 02 July 2010

Manufacturer:	Nonin Medical, Inc.
Address:	13700 1st Avenue North Plymouth, MN 55441-5443 USA
Model Numbers and Product Designations:	9560 Onyx® II Finger Pulse Oximeter
Device Category(ies):	Telemetry system, pulse oximetry
GMDN Number(s):	36118
Date Added:	May 2008

We herewith declare that the above mentioned finger tip 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 9919:2005, *Medical electrical equipment -- Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use.*

We further declare, under our sole responsibility, that the above mentioned finger tip 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 Product Service GMBH Zertifizierstelle Ridlerstrasse 65 D-80339 München Germany
EC Certificate Number:	G1 09 05 24497 021
Signature:	Kim E. Aves
Name:	Kim E. Aves
Title:	Regulatory Affairs Specialist

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