

## **Declaration of Conformity**

Date: 13 November 2013

Manufacturer: Address:	Nonin Medical, Inc. 13700 1 <sup>st</sup> Avenue North Plymouth, MN 55441-5443 USA
Model Numbers and Product Designations:	2500A PalmSat <sup>®</sup> Pulse Oximeter System
Device Category(ies):	Oximeter, pulse
GMDN Number(s):	17148
Date Added:	January 2005

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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

Notified Body:

TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München Germany

EC Certificate Number:

Kin & Auce

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Signature: Name: Title:

Kim E. Aves Senior Regulatory Affairs Specialist

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