

## Declaration of Conformity

**Date:** 21 July 2014

**Manufacturer/Place of Declaration:** Nonin Medical, Inc.  
**Address:** 13700 1<sup>st</sup> Avenue North  
Plymouth, MN 55441-5443 USA

**Model Numbers and Product Designations:** 2500A  
PalmSat® 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), 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*.

This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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  
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**EC Certificate Number:** G1 13 09 24497 023

**Number:** CE0123

**Signature:**   
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