

Declaration of Conformity

Date: 21 July 2014

Manufacturer/Place of Declaration:

Nonin Medical, Inc.

Address:

13700 1st Avenue North
Plymouth, MN 55441-5443 USA

**Model Numbers and
Product Designations:**

9843, 9847
Digital Pulse Oximeter & CO₂ Detector
System

Device Category(ies):

Oximeter, pulse
Carbon dioxide monitor

GMDN Number(s):

17148
17224

Date Added:

March 2002

We herewith declare that the above mentioned pulse oximeter and CO₂ detector 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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
Ridlerstrasse 65
D-80339 München
Germany

EC Certificate Number:

G1 13 09 24497 023

Signature:



Name:

Kim E. Aves

Title:

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Authorized EC Representative:

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