Declaration of Conformity

Date: 21 December 2018

Manufacturer/Place of Declaration:	Nonin Medical, Inc.
Address:	13700 1st Avenue North Plymouth, MN 55441-5443 USA
Model Numbers and Product Designations:	9590 Onyx® Vantage 9590 Finger Pulse Oximeter
Device Category(ies):	Oximeter, pulse
GMDN Number(s):	17148
Date Added:	02 September 2011

We herewith declare that the above mentioned finger tip 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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

This declaration is the sole responsibility of the above named manufacturer.

Notified Body	TÜV SÜD Product Service GmbH Ridlerstrasse 65 D-80339 München Germany
Number	CE0123
EC Certificate Number:	G1 024497 0030 Rev. 00
Signature:	Kim E. Aves
Name:	Kim E. Aves
Title:	Principal Regulatory Affairs Specialist

Authorized EC Representative:
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