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:	9550 Onyx® II Finger Tip Pulse Oximeter
Device Category(ies):	Oximeter, pulse
GMDN Number(s):	17148
Date Added:	June 2005

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 80601-2-61:2017, *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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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 024497 0030 Rev. 00
Number	CE0123
Signature:	
Name:	Kim E. Aves
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