

## Declaration of Conformity

**Date:** 21 December 2018

**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:** 9590  
Onyx<sup>®</sup> 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 80601-2-61:2017, *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This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.

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

**Notified Body** TÜV SÜD Product Service GmbH  
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Germany

**Number** CE0123

**EC Certificate Number:** G1 024497 0030 Rev. 00

**Signature:**   
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