# Declaration of Conformity

**Date:** 13 February, 2018

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| **Manufacturer/Place of Declaration:** | Nonin Medical, Inc. |
| **Address:** | 13700 1st Avenue North<br>Plymouth, MN 55441-5443 USA |
| **Model Numbers and** | 9591 |
| **Product Designations:** | Onyx®3 Finger Pulse Oximeter |
| **Device Category(ies):** | Pulse oximeter, battery-powered |
| **GMDN Number(s):** | 45607 |
| **Date Added:** | 13 February, 2018 |

We herewith declare that the above mentioned fingertip pulse oximeter 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), 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* and *DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.*

This declaration applies to all devices manufactured from the date of issuance until it is either superseded by another declaration or withdrawn.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.

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| **Notified Body:** | TÜV SÜD Product Service GmbH<br>Ridlerstrasse 65<br>D-80339 München<br>Germany |
| **EC Certificate Number:** | G1 13 09 24497 023 |
| **Number** | CE0123 |

**Signature:** Kim E. Aves

**Name:** Kim E Aves

**Title:** Principal Regulatory Affairs Specialist

**Authorized EC Representative:**
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