EU Medical Device Directive 93/42/EEC
Declaration of Conformity

Product(s): **Onyx® II Military Fingertip Pulse Oximeter (Model 9550)**
Onyx® Vantage Fingertip Pulse Oximeter (Model 9590)

Manufacturer:	Nonin Medical, Inc.	EU Representative:	MPS GmbH
Address:	13700 1st Avenue North Plymouth MN 55441-5443 USA	Address:	Borngasse 20 35619 Braunfels, Germany

Model(s): Onyx® II Military Fingertip Pulse Oximeter (Model 9550)
Onyx® Vantage Fingertip Pulse Oximeter (Model 9590)

UDI-DI:

Device Model	UDI-DI (GTIN-14)
9550: Onyx® II Military Fingertip Pulse Oximeter	0 0849686 070804
9590: Onyx® Vantage Fingertip Pulse Oximeter	0 0833166 004878

Assessment of Product Based Upon:

Quality System Certification
MDSAP ISO 13485:2016 Certificate No: QS6 024497 0031
Issued By: TÜV SÜD America Inc.

CE Certification
CE Certificate No: G1 024497 0030
Conformity Assessment Route: MDD 93/42/EEC, Annex II, Section 3
Issued By: TÜV SÜD Product Service GmbH (0123)

Product Classification: Product classification based on the requirements of EU MDD Annex IX Rule 10 and EU Guidelines for Classification of Medical Devices MEDDEV 2.4/1:

☐	Class I	☐	Class IIa
☒	Class IIb	☐	Class III

Based on a review of the above documents, we hereby declare under sole responsibility as the manufacturer that the above product complies with the requirements of EU Medical Device Directive 93/42/EEC, as amended (2007/47/EC) and Directive 2011/65/EU of the European Parliament.

Approvals:

DocuSigned by:
Brent Geiger
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Brent Geiger, MS, RAC
Vice President Quality, Regulatory and Program Management

15 November 2021

Rev B