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

Product(s): **Pulse Oximetry Sensors**
Accessories: 8008JFW, 8000JFW, 8001JFW, 8000H

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): See below
UDI-DI: See below

Device Model	UDI-DI (GTIN-14)
8330AA	0 0849686 065886
8000Q2	0 0833166 000757
8000J	0 0833166 004717
8000J-3	0 0833166 002188
8000J, 20CM	0 0833166 003536
8000JFW	0 0833166 000627
8000SS	0 0833166 002317
8000SM	0 0833166 002225
8000SL	0 0833166 002294
8000SS-3	0 0833166 002249
8000SM-3	0 0833166 002232
8000SL-3	0 0833166 002287
8000FC	0 0833166 000719
8000FI	0 0833166 000726
8000AA	0 0833166 000153
8000AA-2	0 0833166 000566
8000AA-3	0 0833166 000191
8000AP	0 0833166 000160
8000AP-2	0 0849686 070897
8000AP-3	0 0833166 000207
8100SL	0 0833166 001907
8100SM	0 0833166 004694
8100SS	0 0833166 004793
8001J	0 0833166 000603
8008J	0 0833166 000610
8000R	0 0833166 000689
6000CA	0 0833166 009965
6000CI	0 0833166 001952
6000CP	0 0833166 001945
6000CN	0 0833166 001969
8000AA-WO2	0 0833166 003222
8000J-WO2	0 0833166 003437
8000SS-WO2	0 0833166 003505
8000SM-WO2	0 0833166 003499
8000SL-WO2	0 0833166 003482
6000CA-WO2	0 0849686 050943
8000Q2 with 3150I	0 0849686 050936

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8000R with 3150I	0 0849686 050929
6100CA	0 0849686 070484
6100CP	0 0849686 070477
6100CI	0 0849686 070460
6100CN	0 0849686 070453
8100AA	0 0849686 070613
8100AP	0 0849686 070606
8100Q2	0 0849686 070637
7000A	0 0833166 001976
7000P	0 0833166 001983
7000I	0 0833166 001990
7000N	0 0833166 002003
6500SA	0 0833166 001846
6500MA	0 0833166 001853
8008JFW	0 0833166 000641
8001JFW	0 0833166 000634
8000H	0 0833166 000573

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 IIb
- ☐ Class IIa
- ☐ Class III

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

- ☒ Class I
- ☐ Class IIb
- ☐ Class IIa
- ☐ 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

18 November 2021

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