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

Product(s): NoninConnect™ Bluetooth® Smart Pulse Oximeter (Model 3230)
Nonin® Finger Pulse Oximeter (Model 3231)
NoninConnect Elite™ Bluetooth® Smart Pulse Oximeter (Model 3240)
Nonin® Arro™ Fingertip Pulse Oximeter (Model 3230R)

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

Model(s): **3230, 3231, 3240, 3230R**
UDI-DI: **3230**: GTIN-14 0 0849686 070392
**3231**: GTIN-14 0 0833166 002997
**3240**: GTIN-14 0 0849686 064872
**3230R**: GTIN-14 0 0849686 050820

**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 of Quality, Regulatory and Program Management

21 October 2021

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