



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

Product(s): Digital Pulse Oximeter (Model 7500)
 Digital Pulse Oximeter (Model 7500FO)
 Digital Pulse Oximeter (Model 7500 Hybrid (Slow) Averaging)

Accessories: Digital Pulse Oximeter Analog Output Cable (Model 7500AC)
 Digital Pulse Oximeter Serial Cable (Model 7500SC)
 Digital Pulse Oximeter Power Supply (Model 7500PS)
 Carrying Case (7500CC)
 Power Cord – EU
 Pole Mount Clamp
 Universal Extension Cable – 1 meter (UNI-EXT-1)
 Universal Extension Cable – 3 meters (UNI-EXT-3)
 Universal Extension Cable – 6 meters (UNI-EXT-6)
 Universal Extension Cable – 9 meters (UNI-EXT-9)
 Universal Right Angle Connector (UNI-RA-0)
 Universal Right Angle Connector – 3 m (UNI-RA-3) Adult, Pediatric Fiber Optic Sensor (30ft)
 Adult, Pediatric Fiber Optic Sensor (30ft)
 Adult, Pediatric Fiber Optic Sensor (20ft)
 Infant, Pediatric Fiber Optic Sensor (30ft)
 Infant, Pediatric Fiber Optic Sensor (20ft)
 Fiber Optic Sensor Finger Wrap
 Fiber Optic Sensor Toe Wrap

Manufacturer: Nonin Medical, Inc.

Address: 13700 1st Avenue North
 Plymouth MN 55441-5443 USA

EU Representative:

Address: MPS GmbH
 Borngasse 20
 35619 Braunfels, Germany

Model(s): **7500, 7500FO, 7500 Hybrid (Slow) Averaging, 7500A, 7500SC, 7500PS, 7500CC, Power Cord, Pole Mount Clamp, UNI- EXT-1, UNI-RA-0, UNI-RA-3, UNI-EXT-3, UNI-EXT-6, UNI-EXT-9, UNI-RA-0, UNI-RA-3, Adult, Pediatric Fiber Optic Sensor (30ft), Adult, Pediatric Fiber Optic Sensor (20ft), Infant, Pediatric Fiber Optic Sensor (30ft), Infant, Pediatric Fiber Optic Sensor (20ft), Fiber Optic Sensor Finger Wrap, Fiber Optic Sensor Toe Wrap**

UDI-DI: 7500: GTIN-14 0 0833166 009798
 7500 Hybrid Averaging: GTIN-14 0 0833166 009798
 7500FO: GTIN-14 0 0833166 009767
 7500A: GTIN-14 0 0833166 000948
 7500SC: GTIN-14 0 0833166 000917
 7500PS: GTIN-14 0 0833166 007558
 7500CC: GTIN-14 0 0833166 008708
 Power Cord: GTIN-14 0 0849686 089400
 Pole Mount Clamp: GTIN-14 0 0849686 086065
 UNI-EXT-1: GTIN-14 0 0833166 001044
 UNI-EXT-3: GTIN-14 0 0833166 001051
 UNI-EXT-6: GTIN-14 0 0833166 001068
 UNI-EXT-9: GTIN-14 0 0833166 001075
 UNI-RA-0: GTIN-14 0 0833166 001082
 UNI-RA-3: GTIN-14 0 0833166 001099
 Adult, Pediatric Fiber Optic Sensor (30ft): GTIN-14 0 0833166 000702



Adult, Pediatric Fiber Optic Sensor (20ft): GTIN-14 0 0833166 000719
 Infant, Pediatric Fiber Optic Sensor (30ft): GTIN-14 0 0833166 000726
 Infant, Pediatric Fiber Optic Sensor (20ft): GTIN-14 0 0833166 000733
 Fiber Optic Sensor Finger Wrap: GTIN-14 0 0833166 000795
 Fiber Optic Sensor Toe Wrap: GTIN-14 0 0833166 000818

Assessment of Product Based Upon:

Quality System Certification

MDSAP ISO 13485:2016 Certificate No: QS6 024497 0031 Rev.01
 Issued By: TÜV SÜD America Inc.

CE Certification

CE Certificate No: G1 024497 0030 Rev.00
 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:

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Class I
 Class IIb

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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:

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Class I
 Class IIb

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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 of Quality, Regulatory and Program Management

06 December 2021