



## Manufacturer's Declaration

In relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to:

- The validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or **Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates)** and/or
- The compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Nonin Medical Inc.
Manufacturer address and contact details	13700 1 <sup>st</sup> Avenue North, Plymouth Minnesota, 55441 USA John Melquist Director Quality Systems & Compliance <a href="mailto:John.Melquist@Nonin.com">John.Melquist@Nonin.com</a> Phone: +1 315 857 7280
Single Registration Number (SRN)	Nonin Actor ID/SRN: US-MF-000008228
Authorized Representative name	MPS Medical Product Service GmbH
Authorized Representative address and contact details	Borngasse 20, 35619 Braunfels, GERMANY Gerhard Frömel European Regulatory Expert <a href="mailto:g.froemel@mps-gmbh.eu">g.froemel@mps-gmbh.eu</a> Phone: +49 (0) 6442 962073
Single Registration Number (SRN)	MDR Actor ID/SRN: DE-AR-000005009
Notified body name	TUV SUD
Notified body number	CE0123
MDD Directive Certificate number to which this confirmation is made	MDD Cert No. G1 024497 0030
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	1 December 2023
End date of extended validity/transition period	31 December 2028



**We, as the manufacturer declare under our sole responsibility:**

- For the above listed Directive Certificate (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met and/or
- The listed device(s) in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service, namely by fulfilling the following conditions:

**Directive Certificate(s) as listed above or in the attached schedule**

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

*Choose applicable statements:*

- Expired before 20 March 2023:
  - Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or
  - A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or
  - A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

*Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:*

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.
- Expired/expires after 20 March 2023:**  
*Choose one applicable statement:*
  - Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and



signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

### Up-Classified devices

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

*Choose one applicable statement:*

- Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.
- We do not intend to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

### Quality Management System (QMS)

*Choose one applicable statement:*

- A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
- A QMS in accordance with Article 10(9) MDR is in place.
- A notified body has issued the attached certificate for the MDR-compliant QMS.

### Device(s) as listed in the attached schedule

- The device(s) continue to comply with the AIMDD or **MDD**.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

### Signed for and on behalf of the manufacturer:

Full Company Name

Nonin Medical Inc.

Location & Date

13700 1<sup>st</sup> Avenue North,  
Plymouth Minnesota, 55441 USA

Signature, Print Name, Title

DocuSigned by:  
*John Melquist* 22-Sep-23  
John Melquist Director Quality  
Systems & Compliance

Contact Details

[John.Melquist@Nonin.com](mailto:John.Melquist@Nonin.com)  
1 315 857 7280



## Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

### Identification of the devices (Pulse Oximeters)

1. Onyx II 9550; Onyx Vantage 9590
2. 3230, 3231, 3240
3. PalmSAT, 2500/2500A
4. 8500
5. CO-Pilot, H500
6. 3150 with BLE, 3150 with USB
7. 9600
8. RespSense II, LS1R; LifeSense II, LS1
9. 7500, 7500FO
10. X-100
11. SenSmart, 3500SP
12. LP XPOD 3012
13. Single use regional sensors: 8004CA, 8004CB, 8004CB-NA, 8204CA
14. Reusable use regional sensors: 8006CA/PI"
15. Single use pulse oximetry sensors: 6000CX Series (CA, CI, CP, CN), 6100CN, 6500 Series (MA, SA), 7000X Series (A, I, P, N)
16. Reusable pulse oximetry sensors: 8330AA, 8000JX Series (8000J, 8000JFW), 8000Q2, 8000SX Series (SS, SM, SL), 8000FX Series (FC, FI), 8000AX Series (AA, AP), 8008JX Series (8008J, 8008JFW), 8100S Series, 800XJ Series (8000J, 8001J, 8008J), 8000R, 8000H

Directive Certificate number to which this confirmation is made  
MDD Cert No. G1 024497 0030

Original expiry date as indicated on the Directive Certificate prior to the extension of the validity  
1 December 2023

Notified Body name and number that issued the Directive Certificate  
TUV SUD, CE0123

Notified Body name and number where the MDR application was lodged/contract signed  
TUV SUD, CE0123 – Signed March 2023

End date of extended validity / transition period  
31 December 2028

Substitute Device(s)  
None