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Inspire trust.**

TÜV SÜD Product Service GmbH · Ridlerstr. 65 · 80339 Munich · Germany

NONIN MEDICAL, INC.
13700 1st Avenue North
55441-5443 PLYMOUTH
USA

Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
24497	71331781	jodi.landrus@tuvsud.com Landrus Jodi	+1 763 401 9428	2024-01-29	1 of 8

**TÜV SÜD Product Service GmbH
Confirmation Letter
CL 024497 0032 Rev. 00**

Reference: 71331781 | TPS1414 | 2009000

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 (in the following referenced as MDR) as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

With this letter TÜV SÜD Product Service GmbH, designated under MDR and identified by the number 0123 on NANDO, confirms that we have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the above stated manufacturer with the following SRN Number:

SRN Number: Nonin Actor ID/SRN: US-MF-000008228

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.

- Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive.
- Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but TÜV SÜD Product Service GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

Registered Office: Munich
Trade Register Munich HRB 85 742
UniCredit Bank AG · BIC HYVEDEMMXXX
IBAN DE13 7002 0270 0048 8522 11
VAT ID No. DE129484267
Information pursuant to § 2 [1] DL-InfoV
(Germany) at tuvsud.com/imprint

Supervisory Board:
Holger Lindner (Chairman)
Board of Management:
Walter Reithmaier (CEO)
Patrick van Welij

TÜV SÜD Product Service GmbH
Certification body for medical Products
Ridlerstr. 65
80339 Munich
Germany

tuvsud.com/ps
Hotline: +49 89 50084-747





If devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that:

- the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or
- provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively.

The transition timelines in accordance Article 120 (3) of MDR that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120 (3c) of MDR, are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices (except sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition, measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

The issuance of the first confirmation letter is free of charge. We reserve the right to invoice further copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=CL_024497_0032_Rev.00

In case of inquiries please contact medical_devices@tuvsud.com.

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
29th January 2024

TÜV SÜD Product Service GmbH
Medical and Health Services

TÜV SÜD Product Service GmbH
Medical and Health Services

A handwritten signature in black ink, appearing to read 'Jodi Landrus'.

Jodi Landrus
Conformity Assessment Responsible (CARE)

A small rectangular digital signature stamp with a grey background and the name 'Junaid' written in blue.

Tunde Junaid
2024.01.29 17:04:39
+01'00'

Tunde Junaid
Application Reviewer



Table 1: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<p>PalmSAT & PalmSAT A</p> <p>Basic UDI-DI: 833166250083</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate #1; NB# 0123</p> <p>EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>LP XPOD</p> <p>Basic UDI-DI: 83316630127Q</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p> <p><input type="checkbox"/> Class III implantable custom-made-device</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate #1; NB# 0123</p> <p>EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023</p> <p>or</p> <p><input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1)</p> <p>Evidence #1; CA#</p> <p>Evidence #2; CA#</p>
<p>WristOx2 BLE & WristOx2 USB</p> <p>Basic UDI-DI: 833166315085</p>	<p><input type="checkbox"/> Class III</p> <p><input type="checkbox"/> Class IIb implantable (non-exempted)</p> <p><input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted)</p> <p><input type="checkbox"/> Class IIa</p> <p><input type="checkbox"/> Class I devices in sterile condition</p> <p><input type="checkbox"/> Class I devices with measuring function</p>	<p><input checked="" type="checkbox"/> N/A</p> <p>or</p> <p><input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:</p>	<p><input checked="" type="checkbox"/> Certification as follows:</p> <p>Certificate #1; NB# 0123</p> <p>EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023</p>



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class III implantable custom-made-device		or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Model 3230 BLE, Model 3230R Arro, Model 3231 USB & Elite BLE Basic UDI-DI: 833166323084	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
SenSmart Basic UDI-DI: 83316635008A 833166X100FJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Model 7500 & 7500FO Basic UDI-DI: 833166750096	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device		0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Model 8500 Basic UDI-DI: 83316685009D	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Onyx II & Onyx Vantage Basic UDI-DI: 8331669550A3	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Avant Basic UDI-DI: 83316696009R	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted)	<input checked="" type="checkbox"/> N/A or	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
	<input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Co-Pilot Basic UDI-DI: 833166H500CN	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
SenSmart Basic UDI-DI: 833166X100FJ	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Regional Oximetry Sensor Basic UDI-DI: 83316680048U	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#
Pulse Oximetry Sensor Basic UDI-DI: 833166600086	<input type="checkbox"/> Class III <input type="checkbox"/> Class IIb implantable (non-exempted) <input checked="" type="checkbox"/> Class IIb / Class IIb implantable (exempted) <input type="checkbox"/> Class IIa <input type="checkbox"/> Class I devices in sterile condition <input type="checkbox"/> Class I devices with measuring function <input type="checkbox"/> Class III implantable custom-made-device	<input checked="" type="checkbox"/> N/A or <input type="checkbox"/> Identification of the corresponding device under MDD/AIMDD Individual Article number:	<input checked="" type="checkbox"/> Certification as follows: Certificate #1; NB# 0123 EC Certificate, Full Quality Assurance System, Directive 93/42/EEC on Medical Devices (MOD), Annex II excluding (4), (Devices in Class IIa, IIb or III), Cert No. G1 024497 0030 Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or <input type="checkbox"/> Evidence that a competent authority of a Member State had granted acc. MDR, Art.59 (1) or Art.97 (1) Evidence #1; CA# Evidence #2; CA#



Table 2: Devices covered by this letter and for which TÜV SÜD Product Service GmbH is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive: N/A

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified during application review)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
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Confirmation Letter Revision History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024/01/29	71331781	Initial issue



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 st Avenue North, Plymouth Minnesota, 55441 USA John Melquist Director Quality Systems & Compliance John.Melquist@Nonin.com 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 g.froemel@mps-gmbh.eu 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 1st 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
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