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Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 024497 0030 Rev. 00

Manufacturer: **NONIN MEDICAL, INC.**
13700 1st Avenue North
Plymouth MN 55441-5443
USA

EC-Representative: **MPS Medical Product Service GmbH**
Borngasse 20, 35619 Braunfels, GERMANY

Product Category(ies): **Oximeters, Pulse Oximeters, Cerebral Oximeters Breathing Monitors, Non-Invasive Blood Pressure Monitors, ECG Monitors and Non-Sterile Sensors**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 72143491

Valid from: 2018-12-11
Valid until: 2023-12-01

Date, 2018-12-11

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 024497 0030 Rev. 00

Facility(ies):

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

Nonin Medical Inc.
13705 1st Ave., Plymouth MN 55441, USA

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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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.

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

Jodi Landrus
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

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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
PalmSAT & PalmSAT A **Basic UDI-DI: 833166250083**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ **Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ **N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ **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, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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#
LP XPOD **Basic UDI-DI: 83316630127Q**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ **Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ **N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ **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, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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#
WristOx2 BLE & WristOx2 USB **Basic UDI-DI: 833166315085**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ **Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function	☒ **N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ **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, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023

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
	☐ Class III implantable custom-made-device		or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) **☒ Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	**☒ N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	**☒ 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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) **☒ Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	**☒ N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	**☒ 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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) **☒ Class IIb / Class IIb implantable (exempted)** ☐ Class IIa	**☒ N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	**☒ 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 Ila, llb or Ill), 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
	☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device		**0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) **☒ Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	**☒ N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	**☒ 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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) **☒ Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	**☒ N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	**☒ 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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted)	**☒ N/A** or	**☒ 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
	☒ **Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	on Medical Devices (MOD), Annex II excluding (4), (Devices in Class Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ **Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ **N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ **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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) ☒ **Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	☒ **N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ **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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) **☒ Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	**☒ N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	**☒ 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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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**	☐ Class III ☐ Class IIb implantable (non-exempted) **☒ Class IIb / Class IIb implantable (exempted)** ☐ Class IIa ☐ Class I devices in sterile condition ☐ Class I devices with measuring function ☐ Class III implantable custom-made-device	**☒ N/A** or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	**☒ 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 Ila, llb or Ill), Cert No. **G1 024497 0030** Rev. 00, Report No.: 72143491, Valid from: 1DEC2018, Valid until: 1DEC2023 or ☐ 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

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