TÜV SÜD Product Service GmbH · Ridlerstraße 65 · 80339 München · Deutschland

Product Service

Mehr Wert.
Mehr Vertrauen.

Advanced Bionics, LLC
28515 Westinghouse Place
Valencia CA 91355
USA

Your Ref/Name	Our Ref/Name	Tel. /E-Mail	Fax	Date	Page
	713220577, 71326918, 713268126 ID 2023-201	+49 89 5190-2465 Lena.Dollezal@tuvsud.com		23. June 2023	1 von 11

Notified Body Confirmation Letter

Reference: 713220577 | 71326918 | 713268126

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 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that, TÜV SÜD Product Service GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0123 on NANDO, has 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 following manufacturer.

Advanced Bionics, LLC
28515 Westinghouse Place
Valencia CA 91355
USA

SRN Number: US-MF-000019344

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below, see attachment:

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

In the case of 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that: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 in accordance with Article 59(1) of the MDR or
- provided evidence that a competent authority of a Member State had granted an exemption from the applicable conformity assessment procedure in accordance with Article 97(1) of the MDR respectively,

by the 20 Mar 2023 for the relevant devices.

The transition timelines 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 (as amended by EU 2023/607), 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 excluding Well-established technologies (WET - 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 or have a 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)

On behalf of the Notified Body,

TÜV SÜD Product Service GmbH
Medical and Health Services
Signatur: Lena Dollezal
E-Mail: lena.dollezal@tuvsud.com

Dr. Lena-Vanessa Dollezal
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services
Signatur: Hoyer Julia
Hoyer Julia (26. Juni 2023 12:20 GMT+2)
E-Mail: Julia.Hoyer@tuvsud.com

Julia Hoyer
Head of Certification Body - Deputy

Product Service

ATTACHMENT

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

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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
1. Naida CI Q70 & 08400944CI5245Y3	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
2. Naida CI Q30 & 08400944CI5260XX	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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
			☐ 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#
3. Naida CI Q90 & 08400944CI5280Y	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
4. RF cable & 08400944CI5415Y4	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives or

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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		☐ 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#
5. Zn-Air battery Pak & 08400944CI5500XU	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
6. PowerCelTM 110 & 08400944CI5511XZ	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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 that qualify as re-usable surgical instruments ☐ 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#
7. PowerCelTM 170 & 08400944CI5517YD	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
8. PowerCelTM 110 mini & 08400944CI5521Y4	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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 that qualify as re-usable surgical instruments ☐ 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#
9. PowerCelTM 230 & 08400944CI5523Y8	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
10. PowerCelTM 170 mini & 08400944CI5527YG	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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 that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		☐ N/A - Device did not require a Notified Body certificate under Directives 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#
11. Naida CI PowerCelTM Charger & 08400944CI5605YB	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
12. Earhook & 08400944CI5710Y9	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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 placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
13. T-Mic 2 & 08400944CI5835YW	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
14. Naida CI Q90 Acoustic Earhook & 08400944CI5850YS	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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 IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
15. CPI-3 Naida CI Programming Cable & 08400944CI6405Y8	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123 Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#
16. Naida CI AquaCaseTM & 08400944CI7431YG	☐N/A or ☒ Class III ☐ Class IIb implantable non-WET device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD	☐ N/A or ☒ Certification as follows: Certificate #: I7 077725 0009 Rev. 00; NB# 0123

Device name & Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-/ application stage)	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 excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device		Certificate #: I1 077725 0005 Rev. 00; NB# 0123 or ☐ N/A - Device did not require a Notified Body certificate under Directives 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 the TÜV SÜD Product Service GmbH is NOT 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 at the pre-/ application stage)	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
N/A; all devices in scope are subject to Table 1.	☒ N/A or ☐ Class III ☐ Class IIb implantable non-WET device ☐ Class IIb excluding Class IIb implantable non-WET ☐ Class IIa ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments ☐ Class III implantable custom-made device	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD:	☒ N/A or ☐ Certification as follows: Certificate #: Certificate #: or ☐ N/A - Device did not require a Notified Body certificate under Directives 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#

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2023-06-23	713220577, 71326918, 713268126	Initial letter