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

Delta Med S.p.a.
Via Guido Rossa 20
46019 Viadana (MN)
ITALY

Your reference/letter of	Our reference/name	Email	Fax extension	Date	Page
026056	713337832 | 713337823 | 713266413	medical_devices@tuvsud.com	-	2024-07-05	1 of 9

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 026056 0034 Rev. 00

Reference: 713337832 | 713337823 | 713266413

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: IT-MF-000027962

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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)

We reserve the right to invoice any issuance, copies, amendments and / or changes of the confirmation letter according to effort.

For confirmation letter validity see www.tuvsud.com/ps-cert?q=cert:CL 026056 0034 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-07-05

TÜV SÜD Product Service GmbH
Medical and Health Services

Emiliano Gavioli
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Franziska Eckert
2024.07.05
15:09:02 +02'00'

Franziska Eckert
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
8032248900019G	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224890501A9	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224890750AY	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248912009X	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224891410AC	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224891701AS	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248910109Q	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224892210A9	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224892510AQ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224893001A5	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224893250AU	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224893450B6	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224895100AN	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224890751B2	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224890851B7	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248700018S	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224890601AE	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224893969CL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248903019X	☒ Class IIa	☒ N/A	☒ Certification as follows:

			Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224891607AZ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224894486C2	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224892357B8	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248750019V	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
80322488000195	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248810019C	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248820019K	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248830019S	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248831019X	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224883201A4	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224883400AC	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224883500AH	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224883701AV	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224883751BC	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224885000A6	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224875401AH	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224875601AT	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224875201A7	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248342018L	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248343018R	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248350008F	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows:

			Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248352018T	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224885210AK	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224890752B4	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248912019Z	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224891412AG	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224891702AU	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224892511AS	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224895101AQ	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224893451B8	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224893001A5	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224892211AB	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248902019S	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
8032248901019M	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
80322483400088	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224878002AL	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0027 Rev. 01; NB # 0123
803224875801B5	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
803224883301A9	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 Rev. 00; NB # 0123
8032248510003A	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 026056 0022 Rev. 02; NB # 0123
8032248650004H	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G1 026056 0022 Rev. 02; NB # 0123
80322485500046	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 026056 0025 Rev. 02; NB # 0123
8032248600003E	☒ Class IIa	☒ N/A	☒ Certification as follows:

			Certificate # G2 026056 0025 Rev. 02; NB # 0123
8032248471019F	☒ Class I devices with measuring function	☒ N/A	☒ Certification as follows: Certificate # G2MS 061967 0002 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med spa.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
803224849401AC	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
8032248490019Q	☒ Class I devices in sterile condition	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
803224848401A5	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of

			Regulation (EU) 2023/607 (July 2023), section 9.2.
8032248473019R	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
8032248474019W	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
803224848701AL	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
80322484700098	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of

			Regulation (EU) 2023/607 (July 2023), section 9.2.
803224848406AF	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
803224848403A9	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
803224848402A7	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
803224847651AP	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of

			Regulation (EU) 2023/607 (July 2023), section 9.2.
803224848702AN	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.
803224848703AQ	☒ Class IIa	☒ N/A	☒ Certification as follows: Certificate # G2 061967 0001 Rev. 00; NB # 0123 Originally issued to company **Bioengineering Laboratories Srl** which is part of the larger organization of **Delta Med S.p.a.** Therefore, additional transitional provisions are granted based on EU Commission's Q&A on practical aspects related to the implementation of Regulation (EU) 2023/607 (July 2023), section 9.2.

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:

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
Not applicable	☒ N/A	☒ N/A	☒ N/A

Confirmation Letter Version History

Date	TÜV SÜD Product Service GmbH internal reference traceable to each version of the letter	Action
2024-07-05	713337832 | 713337823 | 713266413	Initial issue