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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	Tel. extension/Email	Fax extension	Date	Page
26056	713266413	medical_devices@tuvsud.com		2024-09-13	1 of 5

TÜV SÜD Product Service GmbH
Confirmation Letter
CL 026056 0035 Rev. 00

Reference: 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(MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 0035 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-09-13

TÜV SÜD Product Service GmbH
Medical and Health Services

Emiliano Gavioli
Emiliano Gavioli (Sep 13, 2024 14:53 GMT+2)

Gavioli, Emiliano
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Matthias Mumme
Matthias Mumme (Sep 13, 2024 14:52 GMT+2)

Mumme, Matthias
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
803224848250A8	☒ 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.
803224847901AP	☒ 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.
80322483400088	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
803224878501BB	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
803224876001A4	☒ Class Is	☒ N/A	☒ Certification as follows: Certificates # G2 026056 0027 REV.01 # G2S 026056 0029 REV.00 NB# 0123
803224877001AB	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
803224877601B9	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
803224878001AJ	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
803224879301B8	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
803224882501AC	☒ Class Is	☒ N/A	☒ Certification as follows:

			Certificate # G2S 026056 0029 REV.00 NB# 0123
803224882701AN	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
803224883776BU	☒ Class Is	☒ N/A	☒ Certification as follows: Certificate # G2S 026056 0029 REV.00 NB# 0123
80322483380099 **(REF. code 06409903B)**	☒ Class Is	☒ 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.
8032248336008X	☒ Class Is	☒ 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.
80322483345196	☒ Class Is	☒ 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
2024-09-13	713266413	Initial issue