TÜV SÜD Product Service GmbH · Ridlerstrasse 65 · 80339 Munich · Germany

Product Service

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Your reference/letter of	Our reference/name	Tel. extension/Email	Fax extension	Date	Page
47541	713268365 | 713318001 Massimiliano Folco	+39 3499372006 massimiliano.folco@tuvsud.com	-	2024-02-20	1 of 6

TÜV SÜD Product Service GmbH
Confirmation Letter

CL 047541 0026 Rev. 00

Reference: 713268365 | 713318001

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-000019323

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.

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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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that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 047541 0026 Rev. 00

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

On behalf of the Notified Body TÜV SÜD Product Service GmbH,
2024-02-20

TÜV SÜD Product Service GmbH
Medical and Health Services

Massimiliano Folco
Conformity Assessment Responsible (CARE)

TÜV SÜD Product Service GmbH
Medical and Health Services

Franziska Eckert
2024.02.20
12:00:34 +01'00'

Franziska Eckert
Application Reviewer

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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
Compat Modum Gastric Residual Aspiration Accessory **Basic UDI-DI:** **805609372TD0068C**	☐ 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 # G1 047541 0021 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G10 047541 0024 Rev. 01
Compat enteral feeding tubes, Compat Junior enteral feeding tube, Compat Soft, Compat Soft Junior **Basic UDI-DI:** **805609372TD008A6Y**	☐ 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 # G1 047541 0021 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G10 047541 0024 Rev. 01
Compat enteral feeding tubes with stylet, Compat Soft with stylet, Compat Soft Junior with stylet **Basic UDI-DI:** **805609372TD008B72**	☐ 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 # G1 047541 0021 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G10 047541 0024 Rev. 01
Compat StayPut **Basic UDI-DI:** **805609372TD0098J**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 047541 0021 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G10 047541 0024 Rev. 01

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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 with measuring function ☐ Class III implantable custom-made-device		
Compat DualPort **Basic UDI-DI:** **805609372TD01083**	☐ 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 # G1 047541 0021 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G10 047541 0024 Rev. 01
Compat Buddy enteral extension set **Basic UDI-DI:** **805609372TD01185**	☐ 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 # G1 047541 0021 Rev. 00, NB # 0123
Compat Ella enteral pump set (sterile) **Basic UDI-DI:** **805609372TD012A6K**	☐ 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 # G1 047541 0021 Rev. 00, NB # 0123
Compat Ella enteral pump set (not sterile) **Basic UDI-DI:** **805609372TD012B6M**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☒ Class IIa ☐ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G1 047541 0021 Rev. 00, NB # 0123

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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 with measuring function ☐ Class III implantable custom-made-device		
Compat Standard enteral pump set **Basic UDI-DI:** **805609372TD01389**	☐ 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 # G1 047541 0021 Rev. 00, NB # 0123
Compat Flexibaggle **Basic UDI-DI:** **805609372TD00284**	☐ 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 # G2S 047541 0022 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G11 047541 0025 Rev. 00
Enteral ENFit transition adapters and connectors **Basic UDI-DI:** **805609372TD00488**	☐ 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 # G2S 047541 0022 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G11 047541 0025 Rev. 00
Enteral adapters and connectors **Basic UDI-DI:** **805609372TD0058A**	☐ Class III ☐ Class IIb implantable (non-exempted) ☐ Class IIb / Class IIb implantable (exempted) ☐ Class IIa ☒ Class I devices in sterile condition	☒ N/A or ☐ Identification of the corresponding device under MDD/AIMDD Individual Article number:	☒ Certification as follows: Certificate # G2S 047541 0022 Rev. 00, NB # 0123 Note: devices already certified under MDR with TUV SUD PS, certificate G11 047541 0025 Rev. 00

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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 with measuring function ☐ Class III implantable custom-made-device		

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
2024-02-20	713268365 | 713318001	Initial issue